

EPA Registration 82544-1

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-19-09

Experts In-Processing Signature: M F HARRINGTON Date 3-26-09 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>82544-R</u>		EPA Receipt Date: <u>3-19-09</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)(link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
	MRID 477078			

**Comments:**

The studies associated with  
this admin number passed 86-5  
review

mk30 477078-01 to 477078-13

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web



site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 23, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-407607  
EPA File Symbol or Registration Number: 82544-R  
Product Name: SILVER ASSEMBLY WITH WASHING MACHINE  
EPA Receipt Date: 19-Mar-2009  
EPA Company Number: 82544  
Company Name: SAMSUNG ELECTRONICS CO., LTD.

DOUGLAS A. CZERWONKA  
SAMSUNG ELECTRONICS AMERICA, INC.  
SAMSUNG ELECTRONICS CO., LTD.  
935 NATIONAL PARKWAY, SUITE 93520  
SCHAUMBURG, IL 60173-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A500

NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff  
Information Technology & Resources Management Division

## Fee for Service

846940.~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?  
☐ volpay % Reduction: \_\_\_\_

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. 33

Receipt No.

S-

846940

EPA File Symbol/Reg. No.

82544-R

Pin-Punch Date:

3/19/2009

~~XXXX~~ This item is NOT subject to FFS action.

### Action Code:

Requested: A500

Granted: A500

Amount Due: \$ 11,025

### Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: Tom & Stacy for Team 3 Date: 3/29/09

Remarks:

Mold and Bacteria claims w/o data  
Starting chem data cites RED. Inerts not cleared

# Receipt for Section 3

S: 846940

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 82544 SAMSUNG ELECTRONICS CO., LTD. V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 82544 R Product Name: SILVER ASSEMBLY WITH WASHING MACHIN

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 19-Mar-2009

OPP Rec'd Date: 19-Mar-2009

Front End Date: 20-Mar-2009

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Initial application.  
This is the parent product to "Silver Assembly"

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

# FEE FOR SERVICE

## Rice, Cathy

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**From:** paygovadmin@mail.doc.twai.gov  
**Sent:** Wednesday, March 18, 2009 1:21 PM  
**To:** Rice, Cathy  
**Subject:** Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

### Payment Summary

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 24VBDRFC  
Agency Tracking ID: 74066620837


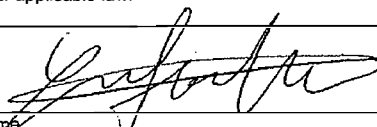
Account Holder Name: Joan E. Oakford  
Transaction Type: Sale  
Billing Address: Keller and Heckman LLP  
Billing Address 2: 1001 G St., NW, Ste. 500 West  
City: Washington  
State/Province: DC  
Zip/Postal Code: 20001  
Country: USA  
Card Type: Master Card  
Card Number: \*\*\*\*\*0061  
Payment Amount: \$11,025.00  
Transaction Date: Mar 18, 2009 1:21:09 PM

Decision Number:  
Registration Number:



Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

		United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number _____
<b>Application for Pesticide - Section I</b>					
1. Company/Product Number 82544- <i>R</i>		2. EPA Product Manager Marshall Swindell		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) <i>Silver Assembly with Washing Machine</i>		PM# Team 33			
5. Name and Address of Applicant (include ZIP Code) Samsung Electronics Co., LTD. 416 Maetan-3dong, Yeongtong-gu Suwon-City, Gyeonggi-do, KOREA 443-742  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____			
<b>Section II</b>					
<input type="checkbox"/> Amendment - Explain Below <input type="checkbox"/> Resubmission in response to Agency Letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency Letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.			
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Initial Registration PRIA Category - A500; Review Time - 9 months Service Fee - \$11025 This is the parent product to "Silver Assembly."					
<b>Section III</b>					
1. <b>Material This Product Will Be Packaged In:</b>					
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit Package wgt. Not Applicable No. per container 1		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____	
* <b>Certification must be submitted.</b>		2. <b>Type of Container:</b> <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 1 unit		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other (_____)			
<b>Section IV</b>					
1. <b>Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>					
Name Catherine Rice		Title Scientist, Keller and Heckman, LLC		Telephone No. (Include Area Code) 202-434-4145	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received  (Stamped)
2. Signature 		3. Title Augustine Kim			
4. Typed Name Vice President, Washing Machine R&D Group		5. Date 3/5/09			

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

January 14, 2016

Coleen Waldenmayer  
Agent for Samsung Electronics Co., LTD  
416 Maetan-3dong, Yeongtong-gu  
Suwon-City, Gyeonggi-do, KOREA 443-742

Subject: Condition of Registration: Waiver Request Storage Stability and Corrosion  
Characteristics Data  
Product Name: Silver Assembly with Washing Machine  
EPA Registration Number: 82544-1  
Application Date: November 10, 2015  
Decision Number: 512592

Dear Ms. Waldenmayer:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at [northern.terria@epa.gov](mailto:northern.terria@epa.gov).

Enclosure: Approved Product Chemistry Review dated January 12, 2016

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", written over a horizontal line.

for

Julie Chao, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

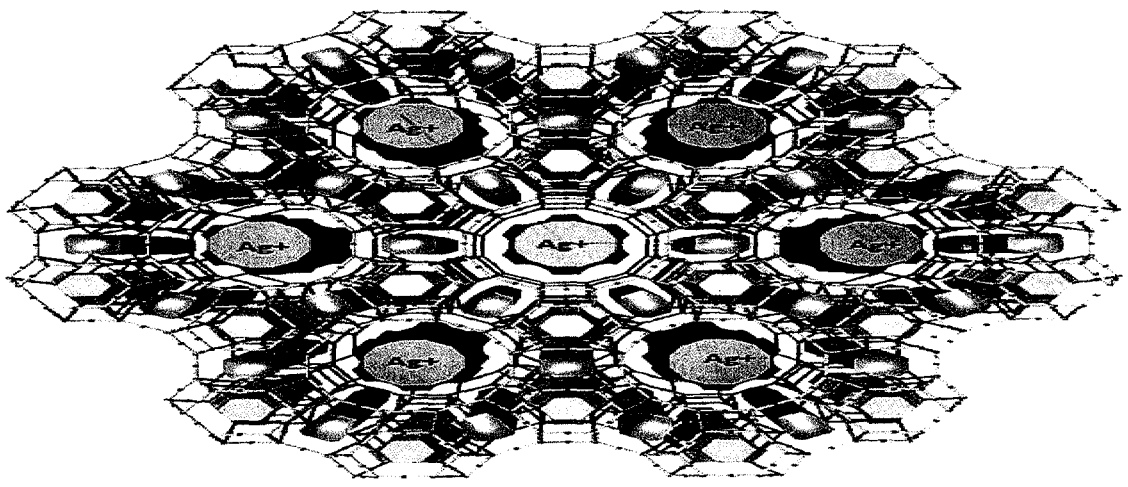


United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

January 12, 2016

EPA Reg#: 82544-1		DP Barcode: 431004	
		Submission #: 977173 E- Sub #:	
Product name: <b>Silver Assembly with Washing Machine</b>		Registrant: Samsung Electronics CO. Ltd	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 02/28/16		PSB received date: 01/05/16	
CTT received date: 01/05/16		Science due date: 12/20/15	
Formulation type: EUP			
Integrated system: <input checked="" type="checkbox"/> Non-integrated system: <input type="checkbox"/> Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>			
Action Code: 570		Date Completed: January 12, 2016	
PC Code	CAS #	Active Ingredient Names	% wt (label)
072599	7440-22-4	Silver	0.011
			
Test Lab: Keller and Heckman LLP.			
MRID(s): 49768401			
Approver: Karen P. Hicks		Approved date: January 12, 2016	
Guideline: Waiver request for Storage Stability Data Requirement OPPTS Guideline Series 830.6317.			
Comments:			

*Handwritten signature and date:* 01/13/16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency


**Office of Pesticide Programs**


**Antimicrobials Division (AD)**

January 12, 2016

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 82544-1  
Product Name: **Silver Assembly with Washing Machine**  
DP#: 431004

**From:** Salvador Rodriguez, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P) 

**Thru:** Karen P. Hicks, CT Team Leader   
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Julie Chao / Terria Northern  
PM Team 33

**Applicant:** Samsung Electronics CO. Ltd

**Action code:** 570

**Due date:** 03/20/16

**Product Formulation**  
**Active Ingredient from label:**

**% by wt.**

Silver.....0.011

## **BACKGROUND:**

The registrant, Samsung Electronics CO. LTD., has submitted a Waiver Request for Storage Stability Data Requirement, to support the registration for the product **Silver Assembly with Washing Machine**. The Product Chemistry Reviewer has received the following documents:

- Application for Pesticide, dated 11/09/15.
- A Waiver request letter, dated 11/10/15. MRID #: 49768401.
- A label, dated 07/30/15.
- Confidential Statement of Formula, dated 06/01/2010, for the basic Formulation. Reference.

## **FINDINGS:**

1. All the components meet the EPA standard certified limits.
2. The CSFs and the label have the same nominal (AI) concentration.

## **CONCLUSIONS:**

The Product Science Branch of Antimicrobials Division finds the Waiver Request for Storage Stability Data Requirement, dated 11/10/15, to support the disinfectant, integrated, non-food use & end-use product **EPARN 82544-1** to be acceptable.

# TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

**49768400**

Samsung Electronics Co., LTD.  
416 Maetan-3dong, Yeongtong-gu  
Suwon-City, Gyeonggi-do, KOREA 443-742

2. Regulatory Action in Support of Which this Package is Submitted

FQPA Action 570 in Response to Conditional Registration  
Silver Assembly with Washing Machine (EPA Reg. No. 82544-1)  
Follow-up to the Agency's July 30, 2015 conditional approval letter

3. Transmittal Date

November 10, 2015

4. List of Submitted Studies

MRID

\_\_\_\_\_ Volume 1 - Administrative Volume (Application, Cover Letter, Data Matrix)

**49768401** Volume 2 - Storage Stability Waiver Request (OCSPP Guideline 830.6317)

Company Official: Coleen Waldenmayer  
Name

Signature

Company Name: Scientist, Keller and Heckman LLP  
Agent for Samsung Electronics Co., LTD.

Company Contact: Coleen Waldenmayer  
Name

202-434-4304  
Phone

DECISION PKG. # 407607  
SUBMISSION BAR CODE # 951848

SUBM. DATE 1/31/15  
REVIEWER (signature)

**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**

FILE SYMBOL/REG NO. 82544-1 PM 33 ACTION CODE ASDD

DESCRIPTOR FOPA NFOPA

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED  
REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

DATE ON APPLICATION 05, 05, 14 EPA RECEIVE DATE 05, 06, 14 PM RECEIVE DATE 05, 08, 14

METHOD OF SUPPORT FORMULATORS EXEMPTION  
[ ] CITE-ALL [ ] SELECTIVE [ ] SUBMITTED [ ] NOT SUBMITTED  
[ ] NOT SUBMITTED [ ] N/A [ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS \_\_\_\_\_

RESPONSE CODE 1810 RESPONSE DATE 07/30/15

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	RASSB	CTT		
EFFICACY	AD	RASSB	EET		

# PROCESSING REQUEST

Reg # 82544-1

Decision #407607

Description: Registration Notice and stamped labeling for Samsung Washing Machine with Silver Assembly

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☒ Dated:

07/30/2015

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 03/05/09

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD



# PROCESSING REQUEST

Phone: 308-6237

Date: 08/03/15

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

**NOTICE OF PESTICIDE:**

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

**EPA Reg. Number:**

82544-1

**Date of Issuance:**

07/30/2015

**Term of Issuance:**

Conditional

**Name of Pesticide Product:**

Silver Assembly with Washing  
Machine

**Name and Address of Registrant (include ZIP Code):**

Mr. John Dubeck  
Samsung Electronics Co., Inc.  
416 Maetan-3dong, Yeongtong-gu  
Suwon-City, Gyeonggi-do, KOREA 443-742

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(B). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:**

John Hebert, Chief  
RMBI, Antimicrobials Division (7510P)

**Date:**

07/30/2015

2. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:

- a. Silver GDCI-072501-1129

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
  4. Make the following label changes before you release the product for shipment:
    - Revise the EPA Registration Number to read, “EPA Reg. No. 82544-1.”
  5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

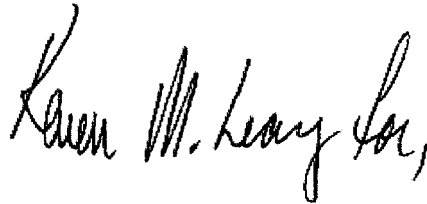
If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/01/2010

Page 3 of 3  
EPA Reg. No. 82544-1  
Decision No. 407607

If you have any questions, please Karen M. Leavy by phone at (703)-308-6237 or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Karen M. Leavy Esq.". The signature is written in a cursive, flowing style.

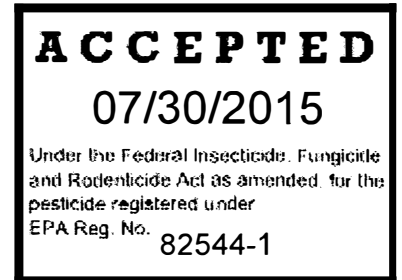
John Hebert  
Branch Chief for,  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure

## Label - Carton

Model [xxx]

**Silver Assembly with Washing Machine**  
**[ABN SilverCare™**  
**ActiFresh**  
**Clean FX**  
**ColdPower**  
**ColdWave**  
**TLC(Total Laundry Clean)**  
**Fresh°**  
**TruFresh]**



Active Ingredient:	
Silver as metallic	0.011%
Other Ingredients	99.989%
TOTAL:	100%

**DISPOSAL:** This washing machine may be disposed of in accordance with federal, state, and local environmental control regulations.

**DIRECTIONS FOR USE:** Refer the Washing Machine User Manual.

Samsung Electronics Co., LTD.	EPA Reg. No. 82544-
416 Maetan-3dong, Yeongtong-gu	EPA Est. No.
Suwon-City, Gyeonggi-do, KOREA 443-742	

NET CONTENTS: One (1) Samsung washing machine

## Label – Appliance

### Model

**Silver Assembly with Washing Machine**  
**[ABN SilverCare™**  
**ActiFresh**  
**Clean FX**  
**ColdPower**  
**ColdWave**  
**TLC**<sub>(Total Laundry Clean)</sub>  
**Fresh°**

When the Silver Assembly is replaced, keep the spent assembly out of the reach of children

[OPTIONAL LANGUAGE: When the Silver cycle is selected and used regularly, this product provides washed clothes that stay fresher longer by significantly reducing the growth of odor-causing bacteria and mold.]

**Active Ingredient:**

Silver as metallic	0.011%
Other Ingredients	99.989%
<hr/>	
TOTAL:	100%

**FOR RESIDENTIAL USE– COMMERCIAL USERS SHOULD NOTIFY THEIR LOCAL WASTE TREATMENT AUTHORITIES BEFORE USE**

**DISPOSAL:** This washing machine may be disposed of in accordance with federal, state, and local environmental control regulations.

**DIRECTIONS FOR USE:** Refer the Washing Machine User Manual.

Samsung Electronics Co., LTD.  
416 Maetan-3dong, Yeongtong-gu  
Suwon-City, Gyeonggi-do, KOREA 443-742

EPA Reg. No. 82544-  
EPA Est. No.

**NET CONTENTS:** One (1) Samsung washing machine

# Washing Machine User Manual - Extract

## For Silver Washing

When the Silver cycle is selected and used regularly, this product provides washed clothes that stay fresher longer by significantly reducing the growth of odor-causing bacteria and mold.

Here's how it works: A grapefruit-sized device alongside the tub uses two pure silver plates the size of large chewing gum sticks as electrodes in the water inlet system. The resulting positively charged silver atoms – Silver ions ( $\text{Ag}^+$ ) – are released into the tub during the final rinse cycle.

Extra delicate blouses, shirts, or even lingerie can be washed with the Silver cycle. When needed, the Silver Assembly must be replaced by a Service Technician.

### To Use:

1. Load the washer.
2. (Press)(Activate)(Select) the Power (button)(knob)(switch).
3. Select a Cycle (by turning the Cycle Selection dial). You cannot choose the Silver cycle with the Wool cycle.
4. (Press)(Activate)(Select) the Silver cycle (button)(knob)(switch).
5. Add detergent in the dispenser tray for main washing, and optionally add fabric softener up to the marked line.
6. (Press)(Activate)(Select) the Start/Pause (button)(knob)(switch). The washer automatically selects optimal washing conditions by sensing the laundry's weight

## FOR RESIDENTIAL USE – COMMERCIAL USERS SHOULD NOTIFY THEIR LOCAL WASTE TREATMENT AUTHORITIES BEFORE USE

The total number of silver cycles run by the washer is displayed when (selecting) (pressing)(activating) the Signal (button)(knob)(switch) and the Silver Ion cycle (button)(knob)(switch) simultaneously while the power is on.

A Service Technician will need to replace the Silver Assembly.  
Contact 1-800-SAMSUNG.

## Optional Claims – SilverCare

When the Silver Ion Option is selected and used regularly, this product:

### Fabric Claims: Under cold wash and no bleach conditions:

- Helps reduce odor on clothing and fabrics.
- Keeps laundry smelling fresher\*, longer when used regularly.
- Regularly used, minimizes odors in clothing, towels, and linens.
- Prevents the growth of odor-causing bacteria on fabrics for 30 days.
- With repeated washings, SilverCare™ reduces the growth of odor-causing bacteria on fabrics.
- Provides a fresher-smelling\* fabric.
- Provides fresher\* fabrics.
- Helps keep your clothes fresher\* longer.
- Provides residual control of odor-causing bacteria on washed fabrics for a month.
- Provides long-lasting control of odor-causing bacteria on washed fabrics for 30 days.
- SilverCare™ prevents the growth of odor causing bacteria on cotton fabrics for several weeks.
- Keeps your laundry smelling fresh\* and clean.

### Washer (drum) Claims: Under cold wash and no bleach conditions:

- Minimizes odors where they hide – in the moist areas inside your washer.
- Provides long lasting control of odor-causing bacteria and/or mold in standing water areas inside your washer for a month.
- Eliminates the growth of odor-causing bacteria and/or mold in washer's water system for 30days.
- Provides a fresher-smelling\* washer.
- Provides a fresher\* washer.
- Kills odor-causing bacteria and/or mold in the water in the drum.
- Reduces the growth of odor-causing bacteria and/or mold in the water in the drum.
- Keep your washer fresh\* and clean

\*References to “fresh” or “fresher” refer to the reduction of odor-causing bacteria and/or mold.



# Washing Machine User Manual - Extract

## Silver Ionizing Process:

When the Silver cycle is selected, silver ions are released during the final rinse process at a controlled rate to provide the benefits of washed clothes that stay fresher longer by reducing the growth of odor-causing bacteria and by significantly reducing the odor-causing mold and bacteria from the washer.

### Silver ionizing process - Technical Specification:

Silver concentration :  $320 \pm 40$  ppb in final rinse water  
Ionization time : 60 ~ 120 sec.  
Ionization current :  $65 \pm 3$  mA.  
Ionization voltage : 0~36V (Automatically adjusted to maintain ionization rate (current) within specified limits).

### Ionization process - Operating range - incoming water:

Inlet water Pressure: 15 PSI – 120 PSI  
Water hardness : 50 -300ppm

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision#:</b> 407861	<b>Registration#:</b> 82544-E - R	<b>Petition #:</b>
<b>Fee Category:</b> A500.1	<b>PRIA Decision Time Frame:</b> 270 days	
<b>Submitted by:</b> Karen Leavy	<b>Branch:</b> RMBI	<b>Date:</b> 07/6/10
<b>Company:</b> Samsung Electronics Co., LTD.		
<b>Original Due Date:</b> 07/09/10	<b>Proposed New Due Date:</b> 08/09/11	
<b>Previous Negotiated Due Dates:</b> No		
<b>Is the "Fix" in-house?</b> No	<b>If not, date "Fix" expected:</b> 03/09/11	
<b>Issue (describe in detail):</b> SamSung submitted an application for registration for the silver assembly to the Agency for our review. This is the child of the parent application for registration under EPA File Symbol 82544-R. This silver assembly is a silver ion generator that contains a pair of silver electrodes. When this silver cycle is selected by the consumer, the silver plates release silver ions. The company makes claims that the release of the silver ions makes the clothes look cleaner and smell fresher. For this product, John Dubeck, regulatory consultant for Samsung submitted product chemistry, acute toxicity data as well as administrative materials needed to complete this application for registration.		

**Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):** On November 11<sup>th</sup>, 2009, Cathy Rice, regulatory consultant for Samsung was informed of all the product chemistry deficiencies. A copy of the Analytical Method needed to be submitted for Agency review. Product Chemistry, Group B, needed to be submitted for Agency review. A revised Confidential Statement of Formula must be resubmitted indicating the total weight of the product. In order to satisfy the efficacy data guidelines for this proposed formulation, clarification of the intended measurable outcome must be submitted to the Agency for our review. In addition, an explanation for the observed "no reductions: comment, the consistent low log reductions for S. aureus, and justification for the submitted data to support these claims for a lower log reduction must be submitted to the Agency for our review. Both the product chemistry as well as the efficacy review listed several labeling revisions. Since both reviewers listed revisions, a corrected product label incorporating the listed revisions must be submitted to the Agency for our review. On February 9, 2010, rebuttal letter was submitted to clarify all the deficiencies as per the Agency efficacy review. On February 9, 2010, product chemistry data, Group B, as well as a revised label was submitted to the Agency for our review. The product chemistry as well as the efficacy data requirements have been satisfied. However, the RASSB risk assessment indicates that a saliva study would be needed to address the MOE target. On June 21<sup>st</sup>, 2010, John Dubeck and Cathy Rice of Keller and Heckman participated in a conference call to discuss the science deficiencies. Both regulatory consultants indicated that the company would generate a saliva study. In order for the company to generate the saliva study, Samsung is requesting a 13 month time extension (08/09/11) from the PRIA due date of July 9, 2010. This would ensure that the company has enough time to generate, submit and the Agency complete its review of the data.

CONCURRENCES							
<b>SYMBOL</b>	7510 P	7510 P					
<b>SURNAME</b>	Edwards	JHF					
<b>DATE</b>	7/6/10	7/6/2010					

**“75 Day” Letter sent? / ☒ No and reason for none?**

**Rationale for Proposed Due Date:** The 13 month time extension of (08/09/11) from the previous negotiated due date of (07/09/10) allow the company to generate a saliva study.

**Summary of Deficiency Type(s):**                      **Not Submitted (N)**      **Deficiencies (D)**

**Product Chemistry:**   D   **Acute Tox:**    **Efficacy:**   D   **Labeling:**    **D Other (describe):** D; based on RASSB Risk Assessment

**Registrant notified that this is the last negotiation?**    Yes   X   NO Why Not?

**Company will have discussions with the RASSB review section concerning a testing protocol in order to generate a saliva study to satisfy the data gap(s) as identified in the RASSB risk assessment.**

**Approve:**

**Disapprove:**

**If disapproved, action to be taken:**

**OD or DOD Signature:**

**Date:**

7-8-10

FW: Revised Request for PRIA Extension - Silver Assembly with Washing Machine (EPA File Symbol 82544-R) and Silver Assembly (EPA File Symbol 82544-E)

Karen Leavy

to:

Dennis Edwards, Marshall Swindell

07/06/2010 06:29 AM

Show Details

Good Morning Dennis/Marshall,

I sent revised time extension write ups for the -R & -E. Hopefully, you will look at them later today. The time extension request which has been revised by Cathy Rice is below along with the time extension write up attachments. Hope your holiday was a good one!!

KML

-----Forwarded by Karen Leavy/DC/USEPA/US on 07/06/2010 06:30AM -----

To: Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA  
 From: Karen Leavy/DC/USEPA/US  
 Date: 07/01/2010 05:01PM  
 Subject: FW: Revised Request for PRIA Extension - Silver Assembly with Washing Machine (EPA File Symbol 82544-R) and Silver Assembly (EPA File Symbol 82544-E)

Dennis/Marshall,

Here is the revised time extension write ups for 82544-R & -E. The request from Samsung is below.

-----Forwarded by Karen Leavy/DC/USEPA/US on 07/01/2010 05:03PM -----

To: Karen Leavy/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA  
 From: "Rice, Cathy" <Rice@khlaw.com>  
 Date: 07/01/2010 03:08PM  
 cc: "Dubeck, John B." <Dubeck@khlaw.com>, "Novak, Michael" <Novak@khlaw.com>, "Dochul Choi" <d12.choi@samsung.com>, "Michelangelo Troisi" <mtroisi@sea.samsung.com>, "Ravve Vaidhyathan" <ravee.v@samsung.com>, "Douglas A. Czerwonka" <dczerwonka@sea.samsung.com>  
 Subject: FW: Revised Request for PRIA Extension - Silver Assembly with Washing Machine (EPA File Symbol 82544-R) and Silver Assembly (EPA File Symbol 82544-E)

Hi Karen,

On behalf of our client Samsung Electronics Co., LTD, we are requesting a 13-month PRIA extension from July 9, 2010 to August 9, 2011. This extension should allow time for Samsung to address the Agency's concerns and for this new information to be reviewed by the Agency. We are optimistic that the extended time frame for EPA review will include the time required for public comment under the transparency policy.

We anticipate a "fix" date of March 9, 2011. During this time, Samsung will develop a study protocol, submit the protocol to EPA for review, and once an approval is received, Samsung will run the appropriate study.

Catherine Rice  
 Scientist

Tel: 202.434.4145 | fax: 202.434.4646 | rice@khlaw.com

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

**Keller and Heckman LLP**

*Serving Business through Law and Science®*

**Washington, D.C. | Brussels | San Francisco | Shanghai**

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**From:** Michelangelo Troisi [mailto:mtroisi@sea.samsung.com]

**Sent:** Thursday, June 24, 2010 12:52 PM

**To:** Dubeck, John B.; Rice, Cathy

**Cc:** Dochul Choi; Douglas A. Czerwonka

**Subject:** Emailing: 17



Please consider the environment before printing this email.

This message and any attachments may be confidential and/or subject to the attorney/client privilege, IRS Circular 230 Disclosure or otherwise protected from disclosure.

If you are not a designated addressee (or an authorized agent), you have received this e-mail in error, and any further use by you, including review, dissemination, distribution, copying, or disclosure, is strictly prohibited. If you are not a designated addressee (or an authorized agent), we request that you immediately notify us of this error by reply e-mail and then delete it from your system.

<b>Recommendation of Division Directors</b> <b>Negotiated Due Dates</b>			
<b>Decision #:</b> 407607,407861	<b>Registration #:</b> 82544-R,82544-E	<b>Petition #:</b>	
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
<b>Chemical Name:</b> Silver			
<b>Fee Category:</b> A500, A500.1		<b>PRIA Decision Time Frame:</b> 270 days	
<b>Submitted by:</b> Karen Leavy		<b>Branch:</b> OCSPP/OPP/AD	<b>Date:</b> 12/08/2014
<b>Company:</b> Samsung, Inc.			
<b>Original PRIA Due Date:</b> 07/09/2010		<b>Proposed New PRIA Due Date:</b> 05/15/2015	
<b>Previous Negotiated Due Dates:</b> 08/09/2011      12/09/2011      04/15/2012      04/02/2013			
<b>Is the "Fix" in-house?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a		<b>If not, date "Fix" expected:</b>	
<b>Negotiated Due Date Reason:</b>			
<b>Additional Data Required</b>	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
			<input checked="" type="checkbox"/> Other
<b>Data Deficiencies</b>	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
			<input checked="" type="checkbox"/> Other
			<input type="checkbox"/> Toxicology
			<input type="checkbox"/> Not Submitted
<b>Late Risk Assessment</b>	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological		
<b>Interim Consideration</b>	<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other – Comment Field
<b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input checked="" type="checkbox"/>			
<small>OPP/AD must interpret and make a determination on the impact of FDA's study on ionic silver.</small>			
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> On page 2			
<b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
<b>Rationale for Proposed Due Date:</b> OPP/AD needs time to interpret and review FDA's findings.			
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
<b>Approve:</b> <input checked="" type="checkbox"/>		<b>Disapprove:</b> <input type="checkbox"/>	
<b>If disapproved, action to be taken:</b>			
<b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US			<b>Date:</b> 12/09/2014

<b>Decision #:</b> 407607,407861	<b>Registration #:</b> 82544-R,82544-E	<b>Petition #:</b>

**Issue(s) (describe in detail):**

On November 25, 2014 John Dubeck, legal consultant for Samsung was contacted about extending the current PRIA due date from 12/08/2014 to 05/15/2015. Additional time is needed for OPP/AD to review a recent Food and Drug Administration silver ion study and for coordination with FDA. The study data calls into question the long established safety levels of silver and it may have an affect on the risk assessment for this new use.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-14338142537-KL

SUBMITTED on 12/04/2014 at 02:54:01 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

APPROVED on 12/08/2014 at 06:28:31 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 12/08/2014 at 06:28:50 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 12/09/2014 at 11:28:44 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision #:</b> 407607,407861	<b>Registration #:</b> 82544-R,82544-E	<b>Petition #:</b>
<input checked="" type="checkbox"/> See page 2 for additional registration entries		
<b>Chemical Name:</b> Silver		
<b>Fee Category:</b> A500, A500.1		<b>PRIA Decision Time Frame:</b> 9 months
<b>Submitted by:</b> Karen Leavy		<b>Branch:</b> OCSPP/OPP/AD <b>Date:</b> 05/05/2015
<b>Company:</b> Samsung, Inc.		
<b>Original PRIA Due Date:</b> 01/09/2010		<b>Proposed New PRIA Due Date:</b> 07/31/2015
<b>Previous Negotiated Due Dates:</b> 08/09/2011     12/09/2011     04/15/2012     04/02/2013		
<b>Is the "Fix" in-house?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a <b>If not, date "Fix" expected:</b>		
<b>Negotiated Due Date Reason:</b>		
<b>Additional Data Required</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other	
<b>Data Deficiencies</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
<b>Late Risk Assessment</b>	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	
<b>Interim Consideration</b>	<input checked="" type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input checked="" type="checkbox"/> Public Process <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health	
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label <input type="checkbox"/> Administrative-FR Notice <input type="checkbox"/> Other – Comment Field	
<b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)		
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input checked="" type="checkbox"/>		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> On April 24, 2015, John Dubeck, regulatory consultant for Samsung, was contacted about requesting a time extension to allow for the Public Participation Process.		
<b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>		
<b>Rationale for Proposed Due Date:</b> Additional time needed to allow for the Public Participation Process		
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable		
<b>Approve:</b> <input checked="" type="checkbox"/> <b>Disapprove:</b> <input type="checkbox"/>		
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US		<b>Date:</b> 05/15/2015

Recommendation of Division Directors Negotiated Due Dates			
<b>Decision #:</b> 407607 407861	<b>Registration #:</b> 82544-R	<b>Petition #:</b>	
	82544-E		
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
<b>Chemical Name:</b> Silver			
<b>Fee Category:</b> A500, A500.1		<b>PRIA Decision Time Frame:</b> 270 days	
<b>Submitted by:</b> Karen Leavy		<b>Branch:</b> OCSP/OPP/AD	<b>Date:</b> 10/01/2014
<b>Company:</b> Samsung Electronics Co., LTD.			
<b>Original PRIA Due Date:</b> 10/06/2014		<b>Proposed New PRIA Due Date:</b> 12/06/2014	
<b>Previous Negotiated Due Dates:</b> 07/09/2010      08/09/2011      05/09/2012      02/06/2013			
<b>Is the "Fix" in-house?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a		<b>If not, date "Fix" expected:</b>	
<b>Negotiated Due Date Reason:</b>			
<b>Additional Data Required</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other		
<b>Data Deficiencies</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input type="checkbox"/> Not Submitted		
<b>Late Risk Assessment</b>	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological		
<b>Interim Consideration</b>	<input checked="" type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other – Comment Field
<b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input checked="" type="checkbox"/>			
Policy decision based on findings from nano study submitted in support of Samsung's pending registrations.			
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> See page 2			
<b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
<b>Rationale for Proposed Due Date:</b> Policy decision needed to move forward with registration.			
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
<b>Approve:</b> <input checked="" type="checkbox"/>		<b>Disapprove:</b> <input type="checkbox"/>	
<b>If disapproved, action to be taken:</b>			
<b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US			<b>Date:</b> 10/07/2014

<b>Decision #:</b> 407607 407681	<b>Registration #:</b> 82544-R	<b>Petition #:</b>
	82544-E	

**Issue(s) (describe in detail):**

On September 9, 2014, AD met internally to discuss the findings of RASSB's draft review of the study entitled, "Evaluation of Silver Release from the Samsung SilverCare Washer, which was submitted in support of the pending applications for registration.

The draft review of the study show that this Samsung SilverCare Washer releases ionic silver particles. When the "silvercare" cycle is chosen, the washing machine releases ionic silver particles in the wash water. The ionic release is intended to provide the product's pesticidal action. However, the wash water containing ionic silver particles in the presence of chlorine also forms silver nano particles. This formation of silver nano particles is a natural occurring by product of the silver ions reacting in the presence of chlorine. According to the study, 25% of the ionic silver particles become nano. The bigger issue raised by the review of this study is in determining if all silver based products make nano silver particles. If so, what will the Agency use as a determining factor in imposing nano data requirements to these type of product(s)?

This two month time extension would allow AD to finalize the review and meet with upper management to make a policy decision concerning the nano-particle production and whether we would impose nano data requirements to incoming and pending silver based products.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-14274145827-KL

SUBMITTED on 10/01/2014 at 03:54:36 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

TAKEN BACK on 10/02/2014 at 03:03:22 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

SUBMITTED on 10/02/2014 at 03:09:35 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

TAKEN BACK on 10/06/2014 at 11:47:10 AM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

SUBMITTED on 10/06/2014 at 12:09:49 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

APPROVED on 10/06/2014 at 03:28:37 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 10/06/2014 at 03:43:49 PM by CN=Jennifer Mclain/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 10/07/2014 at 06:47:15 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

<b>Decision #:</b> 407607,407861	<b>Registration #:</b> 82544-R,82544-E	<b>Petition #:</b>

**Issue(s) (describe in detail):**

The additional time is needed for public process. It has been determined that this registration action needs to through public process for several reasons. The proposed decision document will discuss that for any source of silver ions, in the presence of salts in natural waters, incidental particles, some of which are nanosized, of silver salts will form. Also, since this is the first time a washing machine has been registered and we expect that Samsung will heavily promote the product, the public may be interested. In order for the proposed decision document to post with a 30 day comment period and allow time for the Agency to respond to comments we request to extend the current PRIA due date of May 15, 2015, to July 31, 2015.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15125131530-KL

SUBMITTED on 05/05/2015 at 02:26:08 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

APPROVED on 05/08/2015 at 05:34:49 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 05/15/2015 at 02:07:12 PM by CN=Jennifer McClain/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 05/15/2015 at 03:01:13 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US

<b>Recommendation of Division Directors</b> <b>Negotiated Due Dates</b>			
<b>Decision #:</b> 407607, 407861	<b>Registration #:</b> 82544-R, 82544-E	<b>Petition #:</b>	
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
<b>Chemical Name:</b> Silver			
<b>Fee Category:</b> A500, A500.1		<b>PRIA Decision Time Frame:</b> 270 days	
<b>Submitted by:</b> Karen Leavy		<b>Branch:</b> OCSPP/OPP/AD	<b>Date:</b> 03/29/2013
<b>Company:</b> Samsung, Inc.			
<b>Original PRIA Due Date:</b> 07/09/2010		<b>Proposed New PRIA Due Date:</b> 06/15/2014	
<b>Previous Negotiated Due Dates:</b> 08/09/2011      12/09/2011      04/15/2012      04/02/2013			
<b>Is the "Fix" in-house?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		<b>If not, date "Fix" expected:</b> 04/13/2013	
<b>Negotiated Due Date Reason:</b>			
<b>Additional Data Required</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other		
<b>Data Deficiencies</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> Not Submitted		
<b>Late Risk Assessment</b>	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological		
<b>Interim Consideration</b>	<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF <input type="checkbox"/> Public Process <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health <input type="checkbox"/> Impurities Review <input type="checkbox"/> Label <input type="checkbox"/> Administrative-FR Notice <input checked="" type="checkbox"/> Other – Comment Field			
<b>Summary of Deficiency Type(s):</b> <input checked="" type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input checked="" type="checkbox"/>			
Company must provide testing protocol to test product to see if formulation contains silver nano-particles.			
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> See page 2			
<b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
<b>Rationale for Proposed Due Date:</b> One year time extension for development of testing protocol.			
<b>Registrant notified that this is the last negotiation?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not Applicable			
<b>Approve:</b> <input checked="" type="checkbox"/>		<b>Disapprove:</b> <input type="checkbox"/>	
<b>If disapproved, action to be taken:</b>			
<b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US			<b>Date:</b> 04/04/2013

<b>Decision #:</b> 407607, 407861	<b>Registration #:</b> 82544-R,82544-E	<b>Petition #:</b>

**Issue(s) (describe in detail):**

On August 2, 2012, the Agency met with Samsung and their consultant to discuss our request that the company analyze the rinse water from their silver washing machine to determine whether the rinse water contains silver nano particles. A Danish journal article reported finding nanosilver particles in rinse water using a Samsung washing machine with a silver electrode. Upon completion of that meeting, the company agreed to contract with a laboratory to develop a testing protocol to generate data that can be used to determine if the rinse water contains silver nanoparticles. Samsung has submitted two protocols which have been reviewed. A number of questions were raised that need to be addressed and to date no final protocol has been accepted.

On March 12, 2013 the Samsung consultant was contacted about the development of their testing protocol. The company has contracted with a lab, JR Lee group, that will receive and test a washing machine. The laboratory is in the process of developing a testing strategy, completing preliminary runs in order to make sure that the protocol can generate the appropriate data, and tweaking the protocol design itself. A revised protocol will be resubmitted shortly. Upon approval of this testing protocol, the corporation should be able to generate data that supports the company's premise that the formulation does not contain silver nano particles. This determination must be made before the Agency can move forward in processing both of Samsung's pending applications for registration.

AD recommends the one year time extension to ensure that the company has enough time to develop a testing protocol and submit it for our review in order to generate the appropriate data needed to determine if the rinse water contains nano particles. At the same time, AD will inform the company in writing that this is the last PRIA renegotiation that will be accepted

**Comment(s):**



# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-13084144532-KL

SUBMITTED on 03/26/2013 at 01:47:29 PM by CN=Karen Leavy/OU=DC/O=USEPA/C=US

APPROVED on 03/29/2013 at 12:21:45 PM by CN=Dennis Edwards/OU=DC/O=USEPA/C=US

APPROVED on 04/03/2013 at 05:01:01 PM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 04/04/2013 at 07:10:56 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

APR 02 2012

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 2, 2012

Keller and Heckman, LLP  
1001 G Street NW  
Suite 500 West  
Washington, DC 20001

Attention: Catherine B. Rice

Subject: Silver Assembly with Washing Machine & Silver Assembly  
EPA Registration Number 82544-R & 82544-E  
Your Submissions Dated March 28, 2012  
EPA Received Dates March 28, 2012

A preliminary review of the submitted particle size protocol finds that it is not acceptable for the reasons described below.

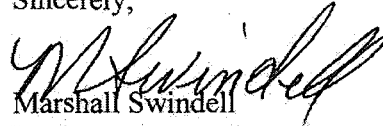
1. The testing protocol does not provide sufficient detail. You must outline as many of the measurement steps as possible so that another independent lab can repeat the sample collection and particle size measurements.
2. The testing protocol did not provide details on how samples will be collected and treated prior to analysis. Details on how samples will be collected and treated prior to analysis need to be submitted to the Agency for our review. The preliminary results state the samples were collected from a 20 L bath, however, no such detail is stated in the protocol. The Agency is requesting that 100 mL samples be collected directly from the effluent of the electrolysis unit.
3. The testing protocol does not provide any detail on the water employed during testing. More details on the water employed during testing must be provided. The Agency would prefer at least three sources of water - deionized water, representative tap water, and Moderately Hard Reconstituted Water (MHRW).
4. The submitted testing protocol did not adhere to the guidance found in the ASTM E2490-09 Standard. This ASTM Standard more than just specifies the instrumentation, it also speaks to the way measurements are completed and verified. For example, Section 8.8.2 states that repeated consecutive measurements should be employed to show that the sample is a stable solution. Other methods such as a concentration matter (sec. 8.7.2) can be used to show that the silver concentration is in the correct range to yield reliable results.

The Agency requests that Samsung adhere to the ASTM Standard guidelines when generating their testing protocol and preliminary data findings.

Since the testing protocol Samsung has provided lacks sufficient detail, the Agency has determined that it cannot be used to satisfy our request for particle size and distribution data for this pending registration application. Therefore, Samsung must resubmit a testing protocol that incorporates the recommendations mentioned above, in our February 15, 2012 letter and that provides greater detail as to how these studies will be conducted.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", written over the printed name.

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7505C)



United States  
Environmental Protection Agency  
Washington, DC 20460

☒  
☐  
☐

**Registration**  
**Amendment**  
**Other**

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 82544-R	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <i>Silver Assembly with Washing Machine</i>	PM# Team 33	
5. Name and Address of Applicant (Include ZIP Code) Samsung Electronics Co., LTD. 416 Maetan-3dong, Yeongtong-gu Suwon-City, Gyeonggi-do, KOREA 443-742  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____	

### Section II

<input type="checkbox"/> Amendment - Explain Below	<input type="checkbox"/> Final printed labels in response to Agency Letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency Letter dated <u>April 2, 2012</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Response to EPA letter of April 2, 2012. Please refer to the cover letter for specifics.

### Section III

1. <b>Material This Product Will Be Packaged In:</b>				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* <b>Certification must be submitted.</b>		If "yes," Unit Package wgt.	No. per container	If "yes," Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			

### Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Catherine Rice	Title Scientist, Keller and Heckman, LLC	Telephone No. (Include Area Code) 202-434-4145
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  <div style="text-align: center;">(Stamped)</div>
2. Signature 	3. Title Registration Counsel/Agent	
4. Typed Name Michael T. Novak	5. Date 6/19/12	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

FEB 15 2012

February 15, 2012

Keller and Heckman, LLP  
1001 G Street NW  
Suite 500 West  
Washington, DC 20001

Attention: Catherine B. Rice

Subject: Nature of Silver Produced by the Silver Assembly with Washing Machine (82544-R)  
and Silver Assembly (82544-E)

The Agency has become aware of an article titled "Characterization of the effluent from a nanosilver producing washing machine" which appeared in the journal *Environment International* (2011, Volume 37, pages 1057 to 1062). In the journal article, the authors present analysis of the effluent from a commercially available washing machine purchased in Norway in 2009, which they described as "provided with silver solution supply device." The authors report finding silver nanoparticles in the effluent from this washing machine with an average concentration of 11 µg/L and with average diameters of 10 nm when operated using the silver wash cycle.

This washing machine was described in the article as the same one identified in the United States Patent 7942024 filed by Samsung on April 16, 2004 and the final patent issued to Samsung on May 17, 2011. In this patent, Samsung describes this washing machine as being equipped with a silver solution supply device and further describes this silver solution as: "A silver solution is a mixture of water and silver ions (Ag<sup>+</sup>), and refers to a colloidal solution containing silver ions in a nano-particle state suspended in the water."

Your applications for registration referenced above state that the Silver Assembly only produces silver ions, not nanosilver. Based on the journal article, claims in the patent, and available advertising on the Samsung website, the Agency is concerned that the Silver Assembly may be producing nanosilver. If this is the case, we will need to modify our approach to reviewing your applications.

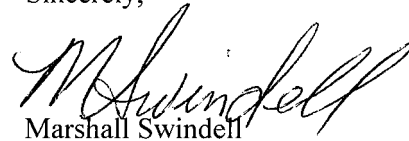
To resolve this issue, EPA requires the following for the Silver Assembly with Washing Machine (82544-R) and Silver Assembly (82544-E):

1. Provide a protocol that covers collecting a sample of water after passing through the Silver Assembly and analyzing this sample for particle size.
2. The particle size analysis shall be performed considering the guidance found in the ASTM E 2490-09 Standard – Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS). If you perform a particle size analysis that does not conform to this standard, the Agency will have to determine if the data generated are acceptable.

3. Provide a clear microscopy image of any particles found in the water sample collected after passing through the Silver Assembly.

Please provide a protocol no later than March 2, 2012. If you have any questions concerning this letter, please contact Jed Costanza at (703) 347-0204.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail.

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobials Division (7510)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION



**DATE:** March 2, 2011

**SUBJECT:** Samsung Silver Assembly with Washing Machine: Human Health Assessment in Support of New Use.

PC Code(s): 072501	DP Barcode(s)/No(s): D384603
Decision No.: 407607	Registration No(s): 82544-R and 82544-E
Petition No(s): NA	Regulatory Action: Human Health Product Registration Review
Risk Assess Type: Screening-Level	Case No(s): 3038
TXR No.: NA	CAS No(s): 7440-22-4
MRID No(s): 482962-01	40 CFR: None

**FROM:** Timothy Leighton, Senior Scientist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**THRU:** Nader Elkassabany, PhD, Branch Chief  
Timothy C. Dole, CIH, Industrial Hygienist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**TO:** Karen Leavy, Team 33  
Marshall Swindell, PM Team 33  
Regulatory Management Branch I (7510P)  
Antimicrobials Division (7510P)

## Executive Summary

There is the potential for dermal and incidental oral exposure to children from fabrics such as clothing/blankets washed in the *Assembly with Washing Machine*. Silver ion has no dermal toxicological endpoints of concern; endpoints are selected for the oral route. Therefore, this assessment is based on the potential for incidental oral exposure (e.g., children mouthing/sucking on clothing and/or blankets). The results of the cotton/polyester clothing and polyester blankets indicate that the short-, intermediate-, and long-term (ST/IT/LT) MOEs for children mouthing fabric are above the target MOEs (MOEs above the target MOE are not of concern), except for the LT MOE for 100 washings of blankets. At 100 washings for the blanket the long-term MOE for mouthing is 2; below the target MOE of 3. The uncertainties in the assessment include, but are not limited to, the number of total washings that will occur per year or per lifetime of the clothing/blanket; the leaching study did not include a detergent wash between each of the test washings which most likely substantially increased the amount of silver ion in the blanket; and the frequency of the user selection of the silver option is unknown (default setting for this product is the “off” position). Taken together, the inputs of this assessment result in a conservative assessment of the risks.

### 1.0 Background

The *Silver Assembly with Washing Machine* product uses two solid silver electrodes as the silver ion generator that releases the silver ion during the final rinse cycle. The silver ion generator is a user-selected option. EPA previously reviewed an assessment of the Samsung *Silver Assembly with Washing Machine* (D364192). In EPA’s previous assessment, potential risks of concern were identified for children mouthing fabrics treated with the silver ion released from this washing machine. Hence the product was not registered. Samsung subsequently modified the *Silver Assembly with Washing Machine* to release less silver and to release the silver ion only during the final rinse cycle. Samsung has also provided additional information on which to estimate potential exposures (e.g., new leaching study that better represents the use, restricted to front-loading machines only, etc). The assessment herein updates the previous EPA assessment using the new leaching data from the modified silver assembly with washing machine (i.e., the new silver assembly releases less silver and releases it only during the final rinse cycle).

### 2.0 Assessment

#### 2.1 Toxicological Endpoint

The following is excerpted from EPA’s previous review of this product (D364192):

##### *1. Short term and intermediate term oral exposure routes:*

*The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.*



*Acceptable MOE = 300 (10x - Intra UF, 10X - inter UF, and 3 x for database UF);*

*Note: The applied database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies.*

## **2. Short term and intermediate term inhalation exposure routes:**

*The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.*

*Acceptable MOE = 1000 (10x - Intra UF, 10X - inter UF, 3 x for database UF, and 3x for route to route extrapolation);*

*Note: The database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies. The safety factor of 3x is applied for extrapolating to an inhalation end-point from an oral study.*

## **3. All dermal exposure routes:**

*No dermal risk assessment is required because silver ions bind to the tissue at the site of dermal contact and no systemic effects are likely to occur. However, warning language such as "Dermal exposure may cause skin color change" should be included in the labeling.*

## **4. Long -term oral exposure route:**

*The long-term oral NOAEL is based the drinking water Secondary Maximum Contaminant Level (SMCL) level of 0.1 mg/L (0.003 mg/kg/day) where the effects are based on skin discoloration and graying of the whites of eyes (Argyria). An additional safety factor of 3 is applied to address the residual uncertainty associated with the missing reproductive, developmental, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver. Acceptable MOE = 3*

## **5. Long-term Inhalation exposure route:**

*The long-term inhalation NOAEL is based on OSHA's 8-hour TWA of 0.01 mg/m<sup>3</sup> (0.001 mg/kg/day) where the effects are based on argyria. An additional safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive, inhalation study, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver.*

*Note: These proposed end-points apply to silver ion only. For other silver complexes (e.g., silver zeolites, nano-silver), AD will evaluate the endpoints on a case by case basis.*

## 2.2 Exposure and Risk Assessment

The route of exposure for this assessment is limited to incidental oral from children mouthing/sucking on treated fabrics such as shirt sleeves, blankets, etc. Although there is the potential for dermal contact, there is no dermal toxicological endpoint of concern. Inhalation exposure is expected to be minimal based on the use pattern (i.e., minimal silver ion being released during the washing cycle).

Typically exposures to treated textiles are the result of contacting clothing that is manufactured with a material preservative and the exposure duration is typically short-term (1 to 30 days). For clothing garments that are used on a routine basis (i.e., once or more per week) and the active ingredient has a long indoor half-life, exposures are also assessed over an intermediate-term time duration (30 days – 6 months). However, this *Silver Assembly Washing Machine* has the potential to release silver ion to all clothing attire on a routine basis if the silver option is selected by the user. The leaching study submitted by Samsung to support this product (MRID 482962-02) indicates that over multiple washes (i.e., up to 50 consecutive washes tested) the silver ion concentration increases in the clothing. Therefore, the potential for exposure to occur on a long-term basis (i.e., > 6 months) is possible. Thus, estimates of short-, intermediate-, and long-term risks are assessed for the post-application washing machine scenario.

The incidental oral exposure can be calculated using the following equation that is based on guidance provided in Human and Environmental Risk Assessment (HERA) Guidance Document (2005):

$$PDD = F \times D \times SE \times F_m / BW$$

Where

PDD	=	Potential daily dose (mg/kg/day)
F	=	fabric residue concentration (ppm/1E+6)
D	=	fabric density (mg/cm <sup>2</sup> )
SE	=	Saliva extraction efficiency (%/100)
F <sub>m</sub>	=	fabric area mouthed (cm <sup>2</sup> /day)
BW	=	body weight (kg)

Where:

- F: The fabric residue concentrations (see Table 1) are based on data provided in Samsung's fabric analysis (MRID 482962-02). This study evaluated multiple test washings. The test article, polyester blanket, was analyzed for silver ion after 10, 20, 30, 40, and 50 wash cycles. The fabric was washed using an eight pound load of laundry with no detergent and no drying between washings. The amount of silver ion in the blanket was extracted using a nitric acid extraction method. In a controlled experiment, this method was demonstrated to have the ability to remove 90.5% of the silver ion. The results of the extraction/leaching study show that the silver ion concentration on the fabric consistently increases with each additional washing. Table 1 includes columns for

measured and predicted residues. The prediction is based on a simple linear regression. The 100 washing event was selected/extrapolated by EPA to represent the high end for yearly washings from a Samsung submitted confidential survey on the frequency of washings.

**Table 1. Measured and Predicted Residues of Silver Ion from Laundered Polyester.**

Number of wash cycles	Measured residue (ppm)	Predicted Residue (ppm)
10	1.33	1.33
20	3.33	3.36
30	5.33	5.40
40	7.67	7.43
50	9.33	9.47
100	Not measured	19.64

Predicted residues (ppm):  $y = 0.2034x - 0.704$ . ( $R^2 = 0.998$ ; slope = 0.2034, intercept = -0.704)

- D: Two fabric densities are assessed. The fabric density of 10 mg/cm<sup>2</sup>, EPA's standard assumption, is based on the density of mixed cotton and synthetic clothing fabrics (HERA, 2005). Samsung also reported (MRID 482962-01) "...a cursory review of baby blankets marketed in the U.S. and found that a majority [baby blankets] are 100% polyester." Although the "cursory review" is not considered a robust survey design, the polyester blanket selected has a fabric density of 29 mg/cm<sup>2</sup> (reported as 250 grams for the 8500 cm<sup>2</sup> polyester blanket) which is 3x higher than for mixed cotton/polyester clothing blend.
- SE: The EPA standard default saliva extraction efficiency is 50% (USEPA, 2001). Because the leaching study submitted by Samsung used a nitric acid extraction of the blanket to remove the silver ion (90.5% extraction efficiency), the saliva extraction efficiency correction is appropriate. A chemical-specific saliva extraction study using a saline solution is being proposed, if necessary, to refine the mouthing extraction efficiency.
- Fm: The surface area of fabric/textile mouthed by children is 100 cm<sup>2</sup>/day (standard assumption).
- BW: The average toddler (3 years old) bodyweight is 15 kg (rounded from 15.1 kg) based on the average of the 50 percentile male and female body weights listed for 42.5 month old children in the CDC growth charts (US EPA, 1997).

## **Results**

The calculation of the short-, intermediate-, and long-term (ST/IT/LT) incidental oral exposures and MOEs are presented in Tables 2 (polyester blanket) and 3 (cotton/polyester clothing). All of the ST and IT oral MOEs are above the target MOE of 300. All of the LT MOEs are also above the target MOE of 3 for the clothing and for 50 or less washings for the blanket. The LT MOE for the blanket that is washed 100 times is 2, below the target MOE of 3.

**Table 2. Estimated Exposures /Risks from Mouthing Laundered Blankets (Polyester).**

#Washings	Silver on Fabric (ppm)	Silver on Fabric (weight fraction)	Fabric Density Polyester (mg/cm <sup>2</sup> )	SA Mouthed (cm <sup>2</sup> )	Oral Exposure (mg/kg/day)	MOEs	
						ST/IT	LT
10	1.33	0.00000133	29	100	0.00013	500,000	23
20	3.33	0.00000333	29	100	0.00032	200,000	9
30	5.33	0.00000533	29	100	0.00052	130,000	6
40	7.67	0.00000767	29	100	0.00074	87,000	4
50	9.33	0.00000933	29	100	0.00090	72,000	3
100	19.64	0.00001964	29	100	0.00190	34,000	2

**Table 3. Estimated Exposures /Risks from Mouthing Laundered Clothing (Cotton/Polyester).**

#Washings	Silver on Fabric (ppm)	Silver on Fabric (weight fraction)	Fabric Density Mixed (mg/cm <sup>2</sup> )	SA Mouthed (cm <sup>2</sup> )	Oral Exposure (mg/kg/day)	MOE	
						ST/IT	LT
10	1.33	0.00000133	10	100	0.00004	1.5E+6	68
20	3.33	0.00000333	10	100	0.00011	580,000	27
30	5.33	0.00000533	10	100	0.00018	360,000	17
40	7.67	0.00000767	10	100	0.00026	250,000	12
50	9.33	0.00000933	10	100	0.00031	210,000	10
100	19.64	0.00001964	10	100	0.00065	99,000	5

### 3.0 Limitations and Uncertainties

The following limitations and uncertainties are listed below to characterize the assessment.

- The survey on the frequency of blanket washings is claimed as confidential by Samsung. However, it can be noted that the vast majority of households wash blankets once per week or less. The upper end of the distribution indicates some households wash blankets more often. This assessment provides exposure and risk estimates at the high end of 100 washings.
- Two fabric densities are reported in this assessment; one for mixed cotton/polyester clothing and one for 100% polyester blankets. Leaching data from the previous *Silver Assembly Washing Machine* study (MRID 477078-11) indicated that the silver ion bonds more to polyester than the cotton mix. Samsung reported in the current study, based on a “*cursory review*”, that the majority of baby blankets in the U.S. are 100% polyester. The

“ *cursory review*” does not appear to be a robust survey, nonetheless, the selection of the polyester material results in the high end of exposure.

- The washing study did not include detergent or drying between washings. In real world use a detergent will be used and will wash away some of the silver ion buildup from previous washings. Not using the detergent in each washing has biased the residues found on the blanket to the high end. The magnitude of the bias is unknown; but thought to be relatively high (perhaps doubling of residues) since Samsung limited the silver ion release to the final rinse cycle only because they found that the silver ion binds to the detergent rather than the fabric. Additionally, Samsung reported in a proposed protocol that “*pretests indicated that the eluted Ag levels could be nearly half if full cycle with detergent is used as compared to rinse only cycle and with no detergent.*”[proposed protocol, undated] Note: pretests were not submitted to EPA, nor are they required at this time.
- The release of the silver ion during the wash cycle is an option selected by the user. The machine’s default setting is set to “off”. The frequency of the selection of this option by users of this washing machine is unknown. Exposures and risks associated with various numbers of washings using the user-selected silver ion release option are provided in this risk assessment – yet no data are available to determine which numbers of washings is the most appropriate.
- The leaching study is based on using a front-loading machine and Samsung intends to only register this type of washing machine.

### 3.0 Conclusion

Using the density of cotton/polyester clothing and polyester blankets, the short-, intermediate-, and long-term (ST/IT/LT) MOEs for children mouthing clothing are above the target MOE (MOEs above the target MOE are not of concern), except for the LT MOE for 100 washings of blankets. At 100 blanket washings the long-term MOE for mouthing is 2; below the target MOE of 3.

There are a number of limitations to consider when assessing the potential exposures/risks in this assessment. Inputs into the assessment that are considered biasing the risks high include: the upper end of the number of total washings (i.e., 100 washings) that will occur per year or per lifetime of the clothing/blanket; not including a detergent wash between each of the test washings is most likely substantially increasing the amount of silver ion in the blanket; and the frequency of the user selecting the silver option is unknown (default setting is “off”). Taken together, the inputs of this assessment result in a conservative assessment of the risks at the 100 washings. Re-running the leaching study using simulated mouthing/saliva extraction as proposed in Samsung’s protocol may not be necessary based on the conservative nature of this assessment.

### 4.0. References

D364192. 2009. Occupational and Residential Exposure and Risk Assessments for the New Use of Silver Ions in Washing Machines. Memorandum from Cassi L. Walls, Ph.D. to Marshall Swindell. Dated November 23, 2009.

HERA, 2005. Human and Environmental Risk Assessment, Guidance Document Methodology, February, 2005 (<http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf>).

MRID 482962-01. Application for Pesticide Registration, Silver Assembly with Washing Machine. EPA File Symbol [82544-R]. Volume 1. Prepared by Keller and Heckman LLP, Submitted by Samsung Electronics Co., LTD. Dated November 16, 2010.

MRID 482962-02. Application for Pesticide Registration, Silver Assembly with Washing Machine. EPA File Symbol [82544-XX]. Volume 2. Prepared by Keller and Heckman LLP, Submitted by Samsung Electronics Co., LTD. Dated November 16, 2010.

USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

USEPA. 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION



**DATE:** March 2, 2011

**SUBJECT:** Samsung Silver Assembly with Washing Machine: Human Health Assessment in Support of New Use.

PC Code(s): 072501	DP Barcode(s)/No(s): D384603
Decision No.: 407607	Registration No(s): 82544-R and 82544-E
Petition No(s): NA	Regulatory Action: Human Health Product Registration Review
Risk Assess Type: Screening-Level	Case No(s): 3038
TXR No.: NA	CAS No(s): 7440-22-4
MRID No(s): 482962-01	40 CFR: None

**FROM:** Timothy Leighton, Senior Scientist  
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**THRU:** Nader Elkassabany, PhD, Branch Chief  
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**TO:** Karen Leavy, Team 33  
Marshall Swindell, PM Team 33  
Regulatory Management Branch I (7510P)  
Antimicrobials Division (7510P)

## Executive Summary

There is the potential for dermal and incidental oral exposure to children from fabrics such as clothing/blankets washed in the *Assembly with Washing Machine*. Silver ion has no dermal toxicological endpoints of concern; endpoints are selected for the oral route. Therefore, this assessment is based on the potential for incidental oral exposure (e.g., children mouthing/sucking on clothing and/or blankets). The results of the cotton/polyester clothing and polyester blankets indicate that the short-, intermediate-, and long-term (ST/IT/LT) MOEs for children mouthing fabric are above the target MOEs (MOEs above the target MOE are not of concern), except for the LT MOE for 100 washings of blankets. At 100 washings for the blanket the long-term MOE for mouthing is 2; below the target MOE of 3. The uncertainties in the assessment include, but are not limited to, the number of total washings that will occur per year or per lifetime of the clothing/blanket; the leaching study did not include a detergent wash between each of the test washings which most likely substantially increased the amount of silver ion in the blanket; and the frequency of the user selection of the silver option is unknown (default setting for this product is the “off” position). Taken together, the inputs of this assessment result in a conservative assessment of the risks.

### 1.0 Background

The *Silver Assembly with Washing Machine* product uses two solid silver electrodes as the silver ion generator that releases the silver ion during the final rinse cycle. The silver ion generator is a user-selected option. EPA previously reviewed an assessment of the Samsung *Silver Assembly with Washing Machine* (D364192). In EPA’s previous assessment, potential risks of concern were identified for children mouthing fabrics treated with the silver ion released from this washing machine. Hence the product was not registered. Samsung subsequently modified the *Silver Assembly with Washing Machine* to release less silver and to release the silver ion only during the final rinse cycle. Samsung has also provided additional information on which to estimate potential exposures (e.g., new leaching study that better represents the use, restricted to front-loading machines only, etc). The assessment herein updates the previous EPA assessment using the new leaching data from the modified silver assembly with washing machine (i.e., the new silver assembly releases less silver and releases it only during the final rinse cycle).

### 2.0 Assessment

#### 2.1 Toxicological Endpoint

The following is excerpted from EPA’s previous review of this product (D364192):

##### 1. *Short term and intermediate term oral exposure routes:*

*The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.*



*Acceptable MOE = 300 (10x - Intra UF, 10X - inter UF, and 3 x for database UF);*

*Note: The applied database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies.*

## **2. Short term and intermediate term inhalation exposure routes:**

*The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.*

*Acceptable MOE = 1000 (10x - Intra UF, 10X - inter UF, 3 x for database UF, and 3x for route to route extrapolation);*

*Note: The database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies. The safety factor of 3x is applied for extrapolating to an inhalation end-point from an oral study.*

## **3. All dermal exposure routes:**

*No dermal risk assessment is required because silver ions bind to the tissue at the site of dermal contact and no systemic effects are likely to occur. However, warning language such as "Dermal exposure may cause skin color change" should be included in the labeling.*

## **4. Long-term oral exposure route:**

*The long-term oral NOAEL is based the drinking water Secondary Maximum Contaminant Level (SMCL) level of 0.1 mg/L (0.003 mg/kg/day) where the effects are based on skin discoloration and graying of the whites of eyes (Argyria). An additional safety factor of 3 is applied to address the residual uncertainty associated with the missing reproductive, developmental, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver. Acceptable MOE = 3*

## **5. Long-term Inhalation exposure route:**

*The long-term inhalation NOAEL is based on OSHA's 8-hour TWA of 0.01 mg/m<sup>3</sup> (0.001 mg/kg/day) where the effects are based on argyria. An additional safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive, inhalation study, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver.*

*Note: These proposed end-points apply to silver ion only. For other silver complexes (e.g., silver zeolites, nano-silver), AD will evaluate the endpoints on a case by case basis.*

## 2.2 Exposure and Risk Assessment

The route of exposure for this assessment is limited to incidental oral from children mouthing/sucking on treated fabrics such as shirt sleeves, blankets, etc. Although there is the potential for dermal contact, there is no dermal toxicological endpoint of concern. Inhalation exposure is expected to be minimal based on the use pattern (i.e., minimal silver ion being released during the washing cycle).

Typically exposures to treated textiles are the result of contacting clothing that is manufactured with a material preservative and the exposure duration is typically short-term (1 to 30 days). For clothing garments that are used on a routine basis (i.e., once or more per week) and the active ingredient has a long indoor half-life, exposures are also assessed over an intermediate-term time duration (30 days – 6 months). However, this *Silver Assembly Washing Machine* has the potential to release silver ion to all clothing attire on a routine basis if the silver option is selected by the user. The leaching study submitted by Samsung to support this product (MRID 482962-02) indicates that over multiple washes (i.e., up to 50 consecutive washes tested) the silver ion concentration increases in the clothing. Therefore, the potential for exposure to occur on a long-term basis (i.e., > 6 months) is possible. Thus, estimates of short-, intermediate-, and long-term risks are assessed for the post-application washing machine scenario.

The incidental oral exposure can be calculated using the following equation that is based on guidance provided in Human and Environmental Risk Assessment (HERA) Guidance Document (2005):

$$PDD = F \times D \times SE \times Fm/BW$$

Where

PDD	=	Potential daily dose (mg/kg/day)
F	=	fabric residue concentration (ppm/1E+6)
D	=	fabric density (mg/cm <sup>2</sup> )
SE	=	Saliva extraction efficiency (%/100)
Fm	=	fabric area mouthed (cm <sup>2</sup> /day)
BW	=	body weight (kg)

Where:

- F: The fabric residue concentrations (see Table 1) are based on data provided in Samsung's fabric analysis (MRID 482962-02). This study evaluated multiple test washings. The test article, polyester blanket, was analyzed for silver ion after 10, 20, 30, 40, and 50 wash cycles. The fabric was washed using an eight pound load of laundry with no detergent and no drying between washings. The amount of silver ion in the blanket was extracted using a nitric acid extraction method. In a controlled experiment, this method was demonstrated to have the ability to remove 90.5% of the silver ion. The results of the extraction/leaching study show that the silver ion concentration on the fabric consistently increases with each additional washing. Table 1 includes columns for

measured and predicted residues. The prediction is based on a simple linear regression. The 100 washing event was selected/extrapolated by EPA to represent the high end for yearly washings from a Samsung submitted confidential survey on the frequency of washings.

**Table 1. Measured and Predicted Residues of Silver Ion from Laundered Polyester.**

Number of wash cycles	Measured residue (ppm)	Predicted Residue (ppm)
10	1.33	1.33
20	3.33	3.36
30	5.33	5.40
40	7.67	7.43
50	9.33	9.47
100	Not measured	19.64

Predicted residues (ppm):  $y = 0.2034x - 0.704$ . ( $R^2 = 0.998$ ; slope = 0.2034, intercept = -0.704)

- D: Two fabric densities are assessed. The fabric density of 10 mg/cm<sup>2</sup>, EPA's standard assumption, is based on the density of mixed cotton and synthetic clothing fabrics (HERA, 2005). Samsung also reported (MRID 482962-01) "...a cursory review of baby blankets marketed in the U.S. and found that a majority [baby blankets] are 100% polyester." Although the "cursory review" is not considered a robust survey design, the polyester blanket selected has a fabric density of 29 mg/cm<sup>2</sup> (reported as 250 grams for the 8500 cm<sup>2</sup> polyester blanket) which is 3x higher than for mixed cotton/polyester clothing blend.
- SE: The EPA standard default saliva extraction efficiency is 50% (USEPA, 2001). Because the leaching study submitted by Samsung used a nitric acid extraction of the blanket to remove the silver ion (90.5% extraction efficiency), the saliva extraction efficiency correction is appropriate. A chemical-specific saliva extraction study using a saline solution is being proposed, if necessary, to refine the mouthing extraction efficiency.
- Fm: The surface area of fabric/textile mouthed by children is 100 cm<sup>2</sup>/day (standard assumption).
- BW: The average toddler (3 years old) bodyweight is 15 kg (rounded from 15.1 kg) based on the average of the 50 percentile male and female body weights listed for 42.5 month old children in the CDC growth charts (US EPA, 1997).

## **Results**

The calculation of the short-, intermediate-, and long-term (ST/IT/LT) incidental oral exposures and MOEs are presented in Tables 2 (polyester blanket) and 3 (cotton/polyester clothing). All of the ST and IT oral MOEs are above the target MOE of 300. All of the LT MOEs are also above the target MOE of 3 for the clothing and for 50 or less washings for the blanket. The LT MOE for the blanket that is washed 100 times is 2, below the target MOE of 3.

**Table 2. Estimated Exposures /Risks from Mouthing Laundered Blankets (Polyester).**

#Washings	Silver on Fabric (ppm)	Silver on Fabric (weight fraction)	Fabric Density Polyester (mg/cm <sup>2</sup> )	SA Mouthed (cm <sup>2</sup> )	Oral Exposure (mg/kg/day)	MOEs	
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30	5.33	0.00000533	29	100	0.00052	130,000	6
40	7.67	0.00000767	29	100	0.00074	87,000	4
50	9.33	0.00000933	29	100	0.00090	72,000	3
100	19.64	0.00001964	29	100	0.00190	34,000	2

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**Table 3. Estimated Exposures /Risks from Mouthing Laundered Clothing (Cotton/Polyester).**

#Washings	Silver on Fabric (ppm)	Silver on Fabric (weight fraction)	Fabric Density Mixed (mg/cm <sup>2</sup> )	SA Mouthed (cm <sup>2</sup> )	Oral Exposure (mg/kg/day)	MOE	
						ST/IT	LT
10	1.33	0.00000133	10	100	0.00004	1.5E+6	68
20	3.33	0.00000333	10	100	0.00011	580,000	27
30	5.33	0.00000533	10	100	0.00018	360,000	17
40	7.67	0.00000767	10	100	0.00026	250,000	12
50	9.33	0.00000933	10	100	0.00031	210,000	10
100	19.64	0.00001964	10	100	0.00065	99,000	5

### 3.0 Limitations and Uncertainties

The following limitations and uncertainties are listed below to characterize the assessment.

- The survey on the frequency of blanket washings is claimed as confidential by Samsung. However, it can be noted that the vast majority of households wash blankets once per week or less. The upper end of the distribution indicates some households wash blankets more often. This assessment provides exposure and risk estimates at the high end of 100 washings.
- Two fabric densities are reported in this assessment; one for mixed cotton/polyester clothing and one for 100% polyester blankets. Leaching data from the previous *Silver Assembly Washing Machine* study (MRID 477078-11) indicated that the silver ion bonds more to polyester than the cotton mix. Samsung reported in the current study, based on a “*cursory review*”, that the majority of baby blankets in the U.S. are 100% polyester. The

“ *cursory review*” does not appear to be a robust survey, nonetheless, the selection of the polyester material results in the high end of exposure.

- The washing study did not include detergent or drying between washings. In real world use a detergent will be used and will wash away some of the silver ion buildup from previous washings. Not using the detergent in each washing has biased the residues found on the blanket to the high end. The magnitude of the bias is unknown; but thought to be relatively high (perhaps doubling of residues) since Samsung limited the silver ion release to the final rinse cycle only because they found that the silver ion binds to the detergent rather than the fabric. Additionally, Samsung reported in a proposed protocol that “*pretests indicated that the eluted Ag levels could be nearly half if full cycle with detergent is used as compared to rinse only cycle and with no detergent.*”[proposed protocol, undated] Note: pretests were not submitted to EPA, nor are they required at this time.
- The release of the silver ion during the wash cycle is an option selected by the user. The machine’s default setting is set to “off”. The frequency of the selection of this option by users of this washing machine is unknown. Exposures and risks associated with various numbers of washings using the user-selected silver ion release option are provided in this risk assessment – yet no data are available to determine which numbers of washings is the most appropriate.
- The leaching study is based on using a front-loading machine and Samsung intends to only register this type of washing machine.

### 3.0 Conclusion

Using the density of cotton/polyester clothing and polyester blankets, the short-, intermediate-, and long-term (ST/IT/LT) MOEs for children mouthing clothing are above the target MOE (MOEs above the target MOE are not of concern), except for the LT MOE for 100 washings of blankets. At 100 blanket washings the long-term MOE for mouthing is 2; below the target MOE of 3.

There are a number of limitations to consider when assessing the potential exposures/risks in this assessment. Inputs into the assessment that are considered biasing the risks high include: the upper end of the number of total washings (i.e., 100 washings) that will occur per year or per lifetime of the clothing/blanket; not including a detergent wash between each of the test washings is most likely substantially increasing the amount of silver ion in the blanket; and the frequency of the user selecting the silver option is unknown (default setting is “off”). Taken together, the inputs of this assessment result in a conservative assessment of the risks at the 100 washings. Re-running the leaching study using simulated mouthing/saliva extraction as proposed in Samsung’s protocol may not be necessary based on the conservative nature of this assessment.

### 4.0. References

D364192. 2009. Occupational and Residential Exposure and Risk Assessments for the New Use of Silver Ions in Washing Machines. Memorandum from Cassi L. Walls, Ph.D. to Marshall Swindell. Dated November 23, 2009. ✓

N: AD Storge RASSB

HERA, 2005. Human and Environmental Risk Assessment, Guidance Document Methodology, February, 2005 (<http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf>).

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MRID 482962-02. Application for Pesticide Registration, Silver Assembly with Washing Machine. EPA File Symbol [82544-XX]. Volume 2. Prepared by Keller and Heckman LLP, Submitted by Samsung Electronics Co., LTD. Dated November 16, 2010.

USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

USEPA. 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.



ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 20, 2011

**MEMORANDUM**

**SUBJECT:** Environmental Fate Assessment for Silver in Washing Machines and Review of Washing Machine Discharge Study

**Cas No.:** 7440-22-4

**DP Barcode(s):** D364888

**FROM:**

James Breithaupt, Agronomist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*James Breithaupt*  
1/20/11

**TO:**

**Dennis Edwards, Chief, RMB 1**  
**Marshall Swindell, Risk Manager**  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**THRU:**

Siroos Mostaghimi, Peer Review  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*Siroos Mostaghimi*

Nader Elkassabany, Chief  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*Nader Elkassabany*

**Chemical Name**  
Silver

**PC Code**  
072501

**CAS#**  
7440-22-4

**Common Name**  
Silver

This memorandum contains the environmental fate assessment for silver used in the final rinse in washing machines. It also contains the DER for MRID 47708909 and the response to waivers in MRID 47707808.

**EXECUTIVE SUMMARY**

Samsung (the registrant) has submitted non-guideline environmental fate data on the discharge from washing machines with the silver release option in the final rinse cycle (47708909). They have also requested waivers other data in MRID 47708908. The study on discharge from

washing machines is unacceptable because of numerous study issues, including calculations that cannot be reproduced, lack of analytical data, and lack of controls. The data that are still required include solubility studies at various pH values from either guideline studies or acceptable literature and modified activated sludge respiration inhibition (850.6800).

## PRODUCT CHEMISTRY (from September 13, 2007 memo)

Table 1 below contains the chemical and physical properties of silver. As a metal, silver is not prone to chemical and microbial degradation per se, but will react with negatively-charged chemical species in soil and water to form complexes.

Table 1. Physical chemical properties of Silver

Parameter	Value	Comment
Molecular Weight (g/mol)	107.87	
Molecular Formula	Ag	
Water solubility (mg/L)	0.0004	At 25°C
Vapor Pressure/volatility (mmHg)	0	At 25°C
Henry's Law Constant (atm-m <sup>3</sup> /mol)	2.45 x 10 <sup>-002</sup>	At 25°C
pKa	Not provided	
Log K <sub>ow</sub> (octanol-water partition coefficient)	0.23	
K <sub>oc</sub> (organic carbon ratio in soil)	14.3	
K <sub>d</sub>	Not provided	
Mobility	Not provided	
BCF	3.162	

## ENVIRONMENTAL CHEMISTRY, FATE, AND TRANSPORT

Silver (CAS 7440-22-4) is the metal with the highest thermal and electrical conductivity. It occurs both as native metal and as distinct mineral phases, mostly as sulfide minerals in complex ores such as proustite (Ag<sub>3</sub>AsS<sub>3</sub>) from where it is mined, processed (primarily by froth flotation), and then refined. Other minerals containing silver include cerargyrite (AgCl), pyrargyrite, and stephanite. The relative abundance of silver in the earth's crust is about 0.08 to 0.2 ppm.

The production and use of silver compounds as batteries (Ag<sub>2</sub>O), catalysts (AgNO<sub>3</sub>, AgCO<sub>3</sub>, AgClO<sub>4</sub>), medical preparations (AgCl), electroplating (AgCN), and photography (silver halides) may result in their release to the environment through various waste streams.

Although silver is, in general, not prone to atmospheric and ordinary oxidation and is resistant to corrosion by weak acids, the presence of sulfur-containing gases in the atmosphere and of sulfide ions in waters can tarnish the surface of silver. Strong, concentrated oxidizing acid solutions can dissolve silver, producing silver(I) species in solution; in alkaline solutions, silver is generally stable. Silver(I) forms soluble complexes with halide anions and with cyanide.



Chloride and bromide ions can react with surface silver oxides to form complexes that are more soluble than the oxides.

The oxidation states of I, II, and III have been identified in silver compounds, but when released to water, the only oxidation state is silver(I). The extent of oxidation (corrosion) of silver metal in aqueous environments is thus determined by the pH, the redox potential, and the temperature of the media. The type and concentration of soluble silver(I) that can form in aqueous media are determined by the nature and concentration of complexing anions present in the media. The formation of insoluble phases, such as silver sulfides, is also determined by the chemical characteristics of the aqueous media.

Silver(I) can readily react with sulfide ions and organic materials bearing thiol groups. Silver sulfides are insoluble, and in sulfide-rich natural waters, the formation of insoluble sulfides serves to immobilize silver. Thiol groups in aquatic sediments also contribute to the removal of silver(I) from the aqueous phase. However, in recent years it has been speculated that the transport and re-deposition of silver in the environment may involve formation of polysulfide silver species.

The speciation of  $\text{Ag}^+$  ions in fresh and marine waters is affected by the concentration of  $\text{Cl}^-$ . In seawater, silver is dominated by the anionic chloro-complex,  $[\text{AgCl}_3]^{-2}$ . In river water, levels of  $\text{AgSH}$  complexes are higher than both  $\text{Ag}^+$  and  $\text{AgCl}$ . The  $K_d$  values for silver suggest that these compounds will have a range of adsorption affinities to suspended solids and sediment. Relatively large amounts of organic colloids will lower the  $K_d$  of silver and remobilize it into the water column. Thus silver contaminated sediments may become a source of dissolved silver to overlying waters due to the remobilization of silver from particulate to dissolved phases. Silver compounds are expected to exist as ions in the environment and therefore volatilization from water surfaces is not expected to be an important fate process. Hydroxide complexes of silver occur at very low concentrations. Inorganic silver ion species will not bioconcentrate in aquatic organisms.

When released to air, silver compounds are expected to exist solely in the particulate phase in the ambient atmosphere. Particulate-phase silver will be removed from the atmosphere by wet and dry deposition.

When released to soil, silver will exist as  $\text{Ag}^+$  ions or as insoluble silver complexes. The partition coefficient ( $K_d$ ) for silver ranges from 16 to 1,300,000, which suggests that silver compounds have a range of mobility. Partitioning of silver compounds are primarily controlled by their speciation both in solution and on soils. Relatively large amounts of organic colloids will lower the  $K_d$  of silver compounds and remobilize the adsorbed silver compounds. Volatilization of silver compounds from moist soil surfaces is not expected to be an important fate process because silver compounds are expected to exist as ions which do not volatilize. Silver compounds are not expected to volatilize from dry soil surfaces based upon their ionic character and low vapor pressures of the non-ionizing compounds.

The germicidal properties of silver metal and silver compounds (such as oxides and salts) have long been recognized. The lethal effect of silver towards microorganisms and other lower life forms, the so-called “oligodynamic effect” is high and second to that of copper. The term “oligodynamic activity” is restricted to solutions in which the metal ion concentration is many orders of magnitude below what would be lethal to higher organisms. Silver-resistant bacteria have been found in urban and industrial polluted sites. It is believed that the resistance to silver is determined by genes on plasmids. The lower affinity of the cells for silver(I) is related to the tendency of silver(I) to be more effectively complexed with extracellular halides, thiols, or organic compounds.

### **Status of Environmental Fate Data Requirements**

The registrant is requesting waivers for a wide range of studies in MRID 47707808. These included:

- Hydrolysis (835.2120)
- Photodegradation in water (835.2240)
- Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)
- Modified Activated Sludge, Respiration Inhibition Test (850.6800)
- Porous Pot Study(835.3220)
- Leaching and Adsorption-Desorption (835.1230 and 835.1240)
- Dissipation in Aquatic Sediment (835.6200) and Monitoring of Representative U.S. Waters (no guideline)
- Metabolism Studies
  - Aerobic Soil Metabolism (835.4100)
  - Anaerobic Aquatic Metabolism (835.4200)
  - Aerobic Aquatic Metabolism (835.4300)
  - Anaerobic Aquatic Metabolism (835.4400)

#### **Hydrolysis (161-1, 835.2120, Waived)**

The hydrolysis data requirement is waived because silver is a metal and will not degrade from the presence of water.

#### **Photodegradation in Water (161-2, 835.2240, Waived)**

The photodegradation in water data requirement is waived because silver is a metal and will not degrade by light, either directly or indirectly.

**Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)  
[Waived]**

These data can be waived because the literature clearly indicates that sorption to sludge and reaction to form insoluble sulfide and thiosulfate complexes are the primary routes of dissipation in wastewater treatment plants. Also, silver is not likely to biodegrade because it is a metal.

**Modified Activated Sludge Respiration Inhibition Test (850.6800)**

These data can be waived because there is a December 1987 Office of Water document with reporting thresholds of 0.25 mg/L and 0.25-5 mg/l inhibition threshold concentration.

**Porous Pot Test (835.3220, Waived)**

This study is not required because the proposed use is classified as indoor, non-food under the current 158 regulations.

**Leaching-Adsorption-Desorption (163-1, 835.1230 and 835.1240, Waived)**

Silver will exist primarily as complexes and most ions will be associated with soil or sediment because of the positive charge of silver and the negative charge of soil.

**Metabolism studies (835.4100, 835.4200, 835.4300, 835.4400, Waived)**

All metabolism studies in soil can be waived for silver because silver is an inorganic ion or a complex that will not degrade. These test data requirements relate to organic compounds that have the potential to mineralize.

**Aquatic Field Dissipation (835.6200, Waived)**

Data on aquatic field dissipation can be waived because silver is an inorganic ion or complex that will not degrade.

**Monitoring of Representative U.S. Waters (no guideline, Waived)**

This data requirement can be waived because silver is a naturally occurring metal that is often found as a complex with negatively-charged ions. There is a National Secondary Drinking Water Regulation of 0.1 mg/L or less for silver.

The DER for MRID 47707809 is attached to this memorandum. If there are any questions, please contact Jim Breithaupt at 703-305-5925 or at [breithaupt.james@epa.gov](mailto:breithaupt.james@epa.gov).

# DATA PACKAGE BEAN SHEET

Date: 03-Feb-2011

Page 1 of 1

Decision #: 407607

DP #: (364888)

PRIA

Parent DP #: 364190

Submission #: 846940

## \*\*\* Registration Information \*\*\*

Registration: **82544-R - SILVER ASSEMBLY WITH WASHING MACHINE**

Company: 82544 - SAMSUNG ELECTRONICS CO., LTD.

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Norman Cook 20995

Sent Date: Calculated Due Date: 09-Aug-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A500) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients:

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 11-May-2009

Due Back:

DP Ingredient:

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: 364190

### Assigned To

### Date In

### Date Out

Organization: AD / RASSB

11-May-2009

10-Dec-2009

Last Possible Science Due Date: 20-Oct-2009

Team Name: RASSB3

11-May-2009

10-Dec-2009

Science Due Date:

Reviewer Name: Breithaupt, James

11-May-2009

10-Dec-2009

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

No Instructions

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES,  
AND TOXIC SUBSTANCES

November 7, 2011

**MEMORANDUM**

**SUBJECT:** **Revised Redacted** Silver Assembly and Washing Machine: Results of Down-the-Drain Modeling of Releases of Silver Ions during the Final Rinse Cycle to Domestic Wastewater Treatment Plants

**TO:** Dennis Edwards, Chief  
Marshall Swindell, Product Manager, Team 33  
Karen Leavy, Regulatory Manager  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**FROM:** Pat Jennings, Environmental Engineer *Pat Jennings 11/7/11*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**THRU:** Donna Randall, Team Leader *Donna M. Randall 11/7/11*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)  
  
Nader Elkassabany, Chief *Nader 11/10/11*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**DP Barcode:** DP395820 and DP395821

**Chemical Name:** Silver

**Registrant:** Samsung Electronics Co., Ltd.

**CAS No.:** 7440-22-4

**PC Code:** 072501

## BACKGROUND AND PURPOSE

Samsung Electronics America, Inc. (SEA) has submitted a request for registration of a silver assembly with washing machine, a silver ion generator which contains as its active ingredient a pair of solid silver plates that serve as electrodes in the water inlet system to front-loading washing machines. When the optional silver cycle is selected, the washing machine releases 4.5 milligrams of ionic silver into the wash tub with about 15 liters of water during the final rinse cycle (Czerwonka 2009). According to Czerwonka (2009), anywhere from 60 to 80 percent of the silver ions generated during the final rinse cycle are retained on garments that are washed, leaving from 20 to 40 percent of silver ions to be released to wastewater from the final rinse cycle that is discharged to wastewater treatment plants. Czerwonka (2009) reported that the amount of silver in wastewater increases with the number of times a garment is washed since as the silver binding sites on a garment fill, the capacity for a garment to bind the silver decreases. As a result, the tendency for silver to be released in wastewater would tend to increase over time when washing clothing that has repeatedly been laundered using the optional silver cycle, resulting in closer to 40 percent silver in rinse water, which corresponds to 1.8 mg silver ions released to wastewater from the final rinse cycle.

Generally, the bioavailability and toxicity of silver to aquatic life has commonly been shown to be related to the activity of the silver ion and/or the concentration of the silver-chloride complex. There is much evidence that free silver ions are highly toxic to a wide variety of freshwater organisms. Metal toxicity to planktonic species such as algae (Lee *et al.* (2005) as cited in Choi *et al.* (2008)) and bacteria (Hu *et al.* (2002) and Hu *et al.* (2003) as cited in Choi *et al.* (2008)) is often governed by the concentrations of aqueous free metal species (Choi *et al.* 2008). Laboratory tests to investigate the potential toxicity of silver ions to aquatic organisms have demonstrated that silver ions are acutely toxic to freshwater invertebrates at concentrations as low as 0.24 µg/L (USEPA, 1987a as cited in USEPA 2011) for unfed cladocerans, acutely toxic to freshwater fish at concentrations as low as 3.9 µg/L (USEPA, 1987a and 1992 as cited in USEPA, 2011), chronically toxic to freshwater invertebrates at concentrations as low as 0.3 µg/L based on 14-d emergence inhibition for an aquatic insect (Howe and Dobson, 2002 as cited in USEPA, 2011), and chronically toxic to freshwater fish at concentrations as low as 0.03 µg/L based on a 13-month NOAEL (EPA, 1987a and Eisler, 1996 as cited in USEPA, 2011). Laboratory tests to investigate the potential toxicity of silver ions to aquatic plants have demonstrated that silver ions are toxic at levels as low as 1.2 µg/L (USEPA, 1987a as cited in USEPA, 2011). These values are reflective of those tests conducted under water quality conditions where silver should be highly bioavailable. Any changes in water quality that would be expected to decrease the activity of the free silver ion would also be expected to decrease the bioavailability of silver. For example, increases in natural organic matter would tend to decrease silver bioavailability and would therefore tend to be associated with reduced silver toxicity. There is research into development and testing of the biotic ligand model (BLM) for use with silver<sup>1</sup> (HydroQual, 2007), as was done with copper. The BLM accounts for individual water quality variables and is based on the premise that toxicity is related to metal bound to a biochemical site (*i.e.*, the biotic ligand), and that binding is related to total dissolved metal

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<sup>1</sup> [http://www.hydroqual.com/wr\\_blm.html](http://www.hydroqual.com/wr_blm.html)

concentrations and complexing ligands in the water (HydroQual, 2007).

The purpose of this memorandum is to evaluate the potential for adverse impacts to freshwater organisms as a result of discharge of silver ions from Samsung's proposed new use of silver assemblies in washing machines that dispense silver ions during the final rinse cycle. To quantitatively estimate the potential for adverse impacts to freshwater organisms from this source of silver ions, the Down-the-Drain model was used. The Down-the-Drain model is a screening-level model developed by EPA/OPPT for estimating concentrations of chemicals in surface waters that may result from the discharge of consumer products in wastewater that subsequently enters domestic wastewater treatment plants (USEPA, 2006). Key input parameters that are needed to run the Down-the-Drain model include: (1) percent removal during wastewater treatment; (2) wastewater treatment plant influent volume; and (3) the concentration of concern for aquatic organisms. For a screening level estimate, results are based on a high-end scenario which represents the averaged probability of exceedance of the 10 percent of WWTPs that have the highest probability of exceedance of the COC following treatment based on the estimated typical daily per capita release of the chemical of concern. These results are expressed as the number of days per year of exceedance of the concentrations of concern determined for key categories of aquatic organisms, including freshwater fish, freshwater invertebrates, and aquatic plants.

## **DISCUSSION**

### **Removal During Wastewater Treatment**

The estimate of percent removal during wastewater treatment used in the Down-the-Drain model was 88.28 percent. This estimate is based on a study of 50 POTWs that was published by the USEPA Office of Water in 1999 (USEPA, 2003). Although data on removal during wastewater treatment is available from other published studies, these data from the study of 50 POTWs are based on a higher number of facilities and are more recent than data from other published studies. This estimate of percent removal of silver is used by OPPT for applications of silver other than nanosilver applications. This estimate is fairly high because silver is strongly sorbed to sludge in wastewater treatment plants and silver has a strong potential to be complexed with various ligands, such as chloride, sulfide, thiosulfate, and dissolved organic carbon (DOC). The extent to which silver entering domestic wastewater treatment plants would be expected to be complexed with various ligands appears to be related to the source of silver entering the wastewater treatment plant influent.

To determine whether the source of silver affects removal of silver and how secondary treatment affects speciation of silver, Lytle (1984) studied fate and speciation of silver in three categories of POTWs: (1) plants that treated municipal sewage and commercial photoprocessing effluents; (2) municipal sewage and non-photographic silver effluents; and (3) municipal sewage with no known silver effluents. The two plants that received silver from photoprocessing operations were reported to achieve 95% removal. The two plants receiving silver from industrial sources were reported to achieve 83% removal. The two plants with no known silver contributors were reported to achieve 48% removal. The average removal efficiency for total

silver at the six treatment plants studied was reported to be 75%. The highest concentrations of free silver ions in treatment plant influents were reported to be associated with the treatment plants that had no known photoprocessing or industrial silver sources. Lytle (1984) reported that substantial amounts of silver were removed from the waste stream and accumulated in the sludge. The POTWs reported to have the highest concentration of silver in their influents, the two plants which treated municipal sewage and photoprocessing effluents, were reported to have the highest concentration of silver in their sludges. Lytle (1984) hypothesized that all of the silver in those sludges would either be in the form of silver sulfide or metallic silver. Lytle (1984) cites sources (Hydroscience, Ind., 1974; JBF Scientific Corp., 1977; Dagon, 1973; and Bard *et al.*, 1976) that contend that silver released from photoprocessing operations is in a stable, silver thiosulfate complex. These sources report that there is excess thiosulfate in photoprocessing effluents available to complex all of the silver which, during secondary waste treatment, is mostly converted to insoluble silver sulfide, with some metallic silver being formed. These sources also report that because of their low solubilities, both silver sulfide and metallic silver are subsequently collected in the settled sludges.

In a survey of photoprocessing facilities, it was found that more than 99% of these facilities in the United States discharge their effluents into municipal sewers leading to publicly owned treatment works (POTWs) (Versar, Inc. 1981 as cited in Pavlostathis and Maeng 1998). According to Pavlostathis and Maeng (1998), the concentration of free silver ions in photoprocessing waters is extremely low and exists either as soluble, undissociated silver-thiosulfate complexes, or as insoluble species, such as silver bromide and silver sulfide. These investigators report that the extent to which ligands (*e.g.*, chloride, sulfide, and thiosulfate) and dissolved organic carbon, which can serve as complexing agents for free silver ions, are present in influents to wastewater treatment plants strongly influences the extent to which silver ions have the potential to remain free or be strongly complexed.

A study by Shafer *et al.* (1998) examined removal, partitioning, and fate of silver and other metals in wastewater treatment plants and the impact of effluent on receiving streams. Included among the wastewater treatment plants examined in this study were some that received wastewaters from major silver end-users. Shafer *et al.* (1998) reported that the high correlation between the percentage of metal removal and partition coefficient indicated that differences among metals in removal efficiency were controlled mainly by metal partitioning (*i.e.*, sorption) to particles removed by settling and/or filtration. Specifically, these investigators reported that a large fraction of silver (*i.e.*, 19-53%) in the filterable (*i.e.*,  $< 1 \mu\text{m}$ ) fraction of POTW effluents was associated with submicron particles or colloids (*i.e.*,  $> 0.05 \mu\text{m}$ ) and the percentage filterable silver was directly related to DOC concentration. These investigators concluded that the aqueous concentrations of silver ions are typically low in wastewater treatment systems and effluent-receiving streams because of the potential for strong complexation of silver ions with various ligands such as chloride, sulfide, thiosulfate, and dissolved organic carbon.

In a study of pollutant removals between POTW influent and primary effluent, POTWs with average influent concentrations exceeding three times each pollutant's detection limit were considered in estimating median removal efficiencies from a database of removal efficiencies for 40 POTWs (USEPA, 1982 as cited in USEPA, 1987b). Based on 4 of 20 POTWs with removal



data, the median removal efficiency of silver through primary treatment was 20 percent. Based on 24 of 26 POTWs with data on removal efficiency, the median removal efficiency between POTW influent and secondary effluent, including secondary clarification, was determined from computer analysis to be 75 percent (USEPA, 1982 as cited in USEPA, 1987b).

### **Wastewater Treatment Plant Influent Volume**

Data on the mass of silver released to wastewater from the final rinse cycle, marketing data provided by Samsung on sales of machines that have the optional silver rinse cycle, data on the life expectancy of front-loading washing machines, and market research data on the number of loads of laundry washed by machine on an annual basis were used to estimate the wastewater treatment plant influent volume used as an input value to the Down-the-Drain model.

According to non-confidential sources of data on appliance life expectancy, front-loading washing machines are reported to last about 11 years. It was assumed that the effective life of front-loading washing machines with silver assemblies sold by Samsung would be 10 years. Based on Confidential Business Information on the percentage of front-loading machines sold in the US that are manufactured by Samsung, estimates of the number of residentially-owned machines, and data on life expectancy of silver ion assemblies in front-loading machines was used to project the number of Samsung front-loading machines with the optional silver rinse cycle that would be sold in the United States over the next 10 years. To estimate the wastewater treatment plant influent volume, the resulting estimate of the number of front-loading washing machines in use 10 years from now was multiplied by the number of loads of laundry washed per family on an annual basis and by the mass of silver ions per load of laundry released to wastewater treatment plants during the final rinse cycle.

It was assumed that each family in the United States has one washing machine. Based on the current US population of approximately 300,000,000 people with 2.59 persons per household, the number of residentially-owned washing machines in the United States was estimated to be 115,830,000. For the purpose of estimating annual wastewater treatment plant influent volume, it was assumed that the average percentage of front-loading machines versus top-loading machines sold in the United States over the next 10 years would be 65 percent front-loading washing machines. Multiplying 0.65 by the number of residential households in the United States, 115,830,000, results in an estimate of 75,289,500 front-loading washing machines in the United States by 2018.

In a memorandum classified as Confidential Business Information (Rice, 2009), a Samsung representative reported that Samsung manufactures only front-loading washing machines. Rice (2009) also reported the Samsung's percentage of sales of the total US market which could be used to determine the percentage of the total US front loading market. Rice (2009) also reported that the silver ion generator feature will not be available on all Samsung washing machines, but did not report the percentage of washing machines that would have the silver ion generator. For the purpose of estimating annual wastewater treatment plant influent volume, it was assumed that all Samsung machines would have the silver ion generator. The percentage of front-loading machines sold by Samsung was multiplied by the projected number of front-loading machines

sold in the US by 2018 (*i.e.*, projected number of front-loading machines sold in the US is 75,289,500).

According to Simmons Market Research Bureau (1982) as cited in Versar, Inc. (1986), the number of loads of laundry washed by a family annually is 338, based on 6.5 machine loads a week. A study by Czerwonka (2009) was used to estimate the mass of silver ions per load of laundry released to wastewater treatment plants during the final rinse cycle. Based on a study performed by Czerwonka (2009) for Samsung Electronics Co., LTD, 4.5 mg of ionic silver is released into the wash tub during the final rinse cycle when the optional silver cycle is selected. Typically, about 60 to 80 percent is retained on clothing leaving about 20 to 40 percent in rinse water that is discharged to a wastewater treatment facility. The percent of silver retained on clothing is proportional to the available binding sites on clothing (Czerwonka 2009). There is a tendency for less binding of silver to clothing with repeated washings in which the silver rinse cycle option is selected (Czerwonka 2009). As a result, silver released in wastewater would tend to increase over time when washing clothing that has repeatedly been laundered using the optional silver cycle, resulting in closer to 40 percent silver in rinse water, which corresponds to 1.8 mg silver ions released to wastewater from the final rinse cycle. Multiplying the estimated number of Samsung washing machines sold through the end of 2018 by the number of loads of wash per family per year (*i.e.*, 338), and the mass of silver ions generated in the final rinse cycle of each load of wash (*i.e.*, 1.8 mg), results in an estimate of a wastewater treatment plant influent volume in kilograms per year in the year 2018, with lesser volumes in preceding years.

An examination of marketing data provided by Samsung on sales of machines that have the optional silver rinse cycle, data on life expectancy of silver assemblies in front-loading washing machines, and market research data on the number of loads of laundry washed by machine on an annual basis indicate that the amount of silver released to domestic wastewater treatment plants from washing machines with the silver rinse cycle option would be relatively low. Ten years from now, if the current percentage of Samsung's sales of front-loading washing machines with the silver assembly continued and the annual number of loads of laundry derived from data reported by Simmons Market Research Bureau is still applicable, the amount of silver entering domestic wastewater treatment plants from machines that have the silver assembly can be estimated in kg/yr.

Note that there is some uncertainty regarding the number of Samsung washing machines with the silver ion generator that will be sold over the next 10 years. For instance, the estimate of washing machines that would release silver ions is based on the current number of households in the United States and does not account for Samsung washing machines with the silver ion generator that would be sold to commercial and institutional establishments nor does it account for machines used by more than one household, such as machines in apartment complexes. However, machines that serve multiple households would be expected to be used more frequently and generate more silver ions per machine than machines used by a single household. The estimate of the number of Samsung washing machines with the silver ion generator also assumes that current sales trends would remain constant over the next 10 years, although Samsung's share of the market could be higher or lower over this time period. It is also assumed that the current population of the United States will remain constant over the next 10 years,

although based on historical trends it is likely that the United States population will continue to increase as it has in the past. The assumption that the percentage of the US front-loading washing machine market would on average be 65 percent over the next 10 years is also uncertain. Although the percentage of front-loading machines is expected to grow, that percentage is unknown.

## RESULTS

The Down-the-Drain model is a screening-level model for estimating concentrations of chemicals in surface waters that may result from the disposal of consumer products into household wastewater. The model estimates the number of days of exceedance of concentrations of concern for aquatic organisms and potential exposures to humans from ingestion of drinking water and fish. Key input parameters and screening-level results from Down-the-Drain modeling are presented in Table 1. For a screening level estimate of exposure to aquatic organisms, results are based on a high-end scenario which represents the averaged probability of exceedance of the 10 percent of WWTPs that have the highest probability of exceedance of the COC following wastewater treatment based on the estimated typical daily per capita release of silver ions. For more information on aquatic toxicity studies that served as the basis for concentrations of concern for aquatic organisms that were used to run the Down-the-Drain model, refer to the memorandum from Donna Randall to Karen Leavy (USEPA 2011). Based on the WWTP influent volume and the assumed removal during wastewater treatment of 88.28%, under a high-end scenario, the Concentrations of Concern (COCs) for acute toxicity to freshwater fish, freshwater invertebrates, and freshwater plants is not expected to be exceeded. Under a high-end scenario, the COC for endangered freshwater fish of 0.2 µg/L is expected to be exceeded less than 1 day per year and the COC for endangered freshwater invertebrates of 0.1 µg/L is expected to be exceeded <1 day per year. The COC for toxicity to endangered freshwater plants, which is the same as the COC for acute toxicity for freshwater plants, is not expected to be exceeded. The table below presents values for input parameters and results for the Down-the-Drain model. Results include high-end estimates of the number of days of exceedance of concentrations of concern for aquatic organisms as well as high-end estimates of potential exposure to humans from ingestion of drinking water and fish.

DOWN-THE-DRAIN MODELING	
MODEL INPUT PARAMETER	VALUE
Estimated WTP Influent Volume (kg/yr)	(Classified as Confidential Business Information since the estimate includes data provided by Samsung on the percentage of Samsung's sales that account for the total US washing machine market and the percentage of the US front loading washing machine market)
WWTP Removal Percentage (%)	88.28 (USEPA 1987b)
BCF	Log 3.162 (1452) (USEPA, 2007)
Acute COC (µg/L) – freshwater fish	2.0 µg/L based on an LC <sub>50</sub> of 3.9 µg/L for <i>Pimephales promelas</i> (i.e., fathead minnow) (USEPA, 1987a, 1992 as cited in USEPA, 2011) multiplied by a risk presumption factor of 0.5
Listed Species COC (µg/L) – freshwater fish	0.20 µg/L based on an LC <sub>50</sub> of 3.9 µg/L for <i>P. promelas</i> (i.e., fathead minnow) (USEPA, 1987a, 1992 as cited in USEPA, 2011) multiplied by a risk presumption factor of 0.05
Acute COC (µg/L) – freshwater invertebrates	1.0 µg/L based on an LC <sub>50</sub> of 1.9 µg/L for <i>Hyallela azteca</i> (i.e., water flea) (Howe and Dobson, 2002 as cited in USEPA, 2011) multiplied by a risk presumption factor of 0.5
Listed Species COC (µg/L) – freshwater invertebrates	0.1 µg/L based on an LC <sub>50</sub> of 1.9 µg/L for <i>H. azteca</i> (i.e., water flea) (Howe and Dobson, 2002 as cited in USEPA, 2011) multiplied by a risk presumption factor of 0.05
Nonlisted aquatic plants COC (µg/L)	2.6 µg/L based on a NOAEC from (USEPA 1987 as cited in USEPA, 2011)
Listed Species aquatic plants COC (µg/L)	1.2 µg/L based on a NOAEC from (USEPA 1987 as cited in USEPA, 2011)
Chronic freshwater fish COC (µg/L)	0.03 µg/L based on an 13-month NOAEL (EPA, 1987a; Eisler, 1996 as cited in USEPA, 2011)
Chronic freshwater invertebrates COC (µg/L)	0.3 µg/L based on a 14-day emergence NOAEC (Howe and Dobson as cited in USEPA, 2011)
Exposure Duration (years of use)	Default value is 57
MODEL RESULTS	
10 <sup>th</sup> %ile Harmonic Mean Stream Dilution Factor	7.95
10 <sup>th</sup> %ile Harmonic Mean Concentration (µg/L)	8.2 x 10 <sup>-04</sup>
10 <sup>th</sup> %ile 7Q10 Stream Dilution Factor	1
10 <sup>th</sup> %ile 7Q10 Concentration (µg/L)	6.52 x 10 <sup>-03</sup>

DOWN-THE-DRAIN MODELING	
MODEL INPUT PARAMETER	VALUE
10 <sup>th</sup> %ile 30Q5 Stream Dilution Factor	1.8
10 <sup>th</sup> %ile 30Q5 Concentration (µg/L)	3.62 x 10 <sup>-03</sup>
Estimated High-end Number of Days per Year Acute COC Exceeded – Freshwater Fish	0
Estimated High-end Number of Days per Year Listed Species COC Exceeded – Freshwater Fish	<1
Estimated High-end Number of Days per year Acute COC Exceeded – Freshwater Invertebrates	0
Estimated Number of Days per Year Listed Species COC Exceeded – Freshwater Invertebrates	<1
Estimated 10 <sup>th</sup> Percentile Lifetime Average Daily Dose from Drinking Water Ingestion (mg/kg/day)	<5 x 10 <sup>-8</sup>
Estimated 10 <sup>th</sup> Percentile Lifetime Average Daily Concentration in Drinking Water (mg/L)	<7 x 10 <sup>-7</sup>
Estimated 10 <sup>th</sup> Percentile Lifetime Average Daily Dose from Ingestion of fish (mg/kg/day)	<1 x 10 <sup>-7</sup>
Estimated 10 <sup>th</sup> Percentile Lifetime Average Daily Concentration in Fish (mg/kg)	<1 x 10 <sup>-3</sup>

## CONCLUSIONS

The contribution of silver to domestic wastewater treatment plants from machines with the silver assembly is small relative to other sources of silver, such as photoprocessing plants, that enter domestic wastewater treatment plant influents. Nonetheless, this source of silver is an additional relatively new source that would tend to increase the amount of silver going to domestic wastewater treatment plants. The potential for silver to enter wastewater treatment plant influents in the form of silver ions must be determined on a case-by-case basis. The predominant source of effluents to wastewater treatment plants and characteristics of the surface water downstream of wastewater treatment plants determines the extent to which ionic silver, the most toxic form of silver other than nanosilver to wastewater treatment plant microorganisms and aquatic life, is present. Wastewater treatment plants which receive effluents from photoprocessing operations and industrial sources would be expected to have low concentrations of silver ions relative to those which receive effluents from no known silver contributors since excess thiosulfate commonly present in photoprocessing effluents would be available to complex silver ions. The presence of silver ions in wastewater treatment plant influents with no known silver contributors could potentially be considerably higher than for wastewater treatment plants that receive effluents from photoprocessing operations and industrial sources given the absence

of various ligands such as chloride, sulfide, thiosulfate, and dissolved organic carbon, which can complex with silver ions. Compared to ionic silver, these silver complexes have been demonstrated to exhibit much lower toxicity to wastewater treatment plant microorganisms.

The Down-the-Drain model was run assuming that, as a worst case, all of the estimated wastewater treatment plant influent volume is in the form of silver ions, the most toxic form of silver other than nanosilver. If some or most of this wastewater treatment plant influent comes from photoprocessing and/or industrial sources, the influent volume of silver in the form of silver ions would be lower due to ligands and/or dissolved organic matter that would be available to complex silver ions. However, if the predominant sources of wastewater treatment plant influent are effluents from no known silver contributors, ligands and/or dissolved organic matter would not be as likely to be available to complex with silver ions and the predominant form of silver entering the wastewater treatment plant would tend to be silver ions. Based on results of the Down-the-Drain model at the estimated wastewater treatment plant influent volume of silver ions and removal of silver during wastewater treatment of 88.28%, no acute or chronic concentrations of concern are exceeded for freshwater fish, freshwater invertebrates, and no exceedances for non-listed or listed freshwater plants.

## REFERENCES

Choi, O, KK Deng, N Kim, L Ross, RY Surampalli, and Z Hu. 2008. Water Research 42:3066-3074. The Inhibitory Effects of Silver Nanoparticles, Silver Ions, and Silver Chloride Colloids on Microbial Growth.

Czerwonka, D. 2009. Determination of Silver Discharge in Wastewater from Washing Machines when the Silver Ion Generator Feature is Selected. EPA MRID 477078-09.

HydroQual, Inc. 2007. Biotic Ligand Model, Windows Interface, Version 2.2.3, User's Guide and Reference Manual. [http://www.hydroqual.com/blm/BLM\\_manual.pdf](http://www.hydroqual.com/blm/BLM_manual.pdf)

Lytle, PE, 1984. Environmental Toxicology and Chemistry, 3:21-30. Fate and Speciation of Silver in Publicly Owned Treatment Works.

Pavlostathis, SG and SK Maeng. 1998. Environmental Toxicology and Chemistry. 17(4): 617-624. Aerobic Biodegradation of a Silver-Bearing Photoprocessing Wastewater.

Rice, C. 2009. Memorandum dated June 15, 2009, from Catherine Rice to Karen Levy entitled "Samsung Silver Assemblies - EPA File Symbols 82544-R and 82544-E". **CONFIDENTIAL BUSINESS INFORMATION**

Shafer, MM, JL Overdier, DE Armstrong. 1998. Environmental Toxicology and Chemistry. 17(4): 630-641. Removal, Partitioning, and Fate of Silver and Other Metals in Wastewater Treatment Plants and Effluent-Receiving Streams.

USEPA. 1987b. United States Environmental Protection Agency, Office of Water Enforcement and Permits. Guidance Manual on the Development and Implementation of Local Discharge Limitations under the Pretreatment Program. <http://www.epa.gov/npdes/pubs/owm0275.pdf>

USEPA. 2003. Development Document for the Final Effluent Limitations Guidelines and Standards for the Metal Products and Machinery Point Source Category. EPA-821-B-03-001. <http://water.epa.gov/scitech/wastetech/guide/mpm/index.cfm>

USEPA. 2006. United States Environmental Protection Agency, Office of Pollution Prevention and Toxics, Exposure Assessment Branch. Exposure and Fate Assessment Screening Tool (E-FAST), Version 2.0 Documentation Manual. April 2006. <http://www.epa.gov/opptintr/exposure/pubs/efast.htm>

USEPA. 2007. Memorandum from Srinivas Gowda to Marshall Swindell, "Environmental Fate Assessment of Silver (0.005%) for New Use Registration (Food Contact Surface Sanitizer)". September 13, 2007. DP338818.

USEPA, 2011. Memorandum (November 7, 2011) from Donna Randall to Karen Leavy, Revised Ecological Assessment of Samsung Electronics Co. Silver Assembly Washing Machine Registration Request and Ecotoxicity Test Data Waivers. DP395491

Versar, Inc., 1986. Standard Scenarios for Estimating Exposure to Chemical Substances During Use of Consumer Products, Volumes 1 and 2, Prepared for U.S. EPA, Office of Toxic Substances, EPA Contract No. 68-02-3968. <http://www.epa.gov/oppt/exposure/pubs/efast2refs.htm>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

July 21, 2010

DP BARCODE: 375932

MRID : 479801-01

SUBJECT: Silver Assembly with Washing Machine  
(Name of Product)

REG. NO.: 82544-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ]

OR

End-use Product [X]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
072501	7440-22-4	*Silver, elemental

\*As a washing machine component

TEST LAB: NA

SUBMITTER: Samsung Electronics Co., LTD

GUIDELINE: OPPTS 830.1800 Enforcement Analytical Method.

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: July 21, 2010

COMMENT:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

July 21, 2010

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 82544-R  
Product Name: Silver Assembly with Washing Machine  
DP Barcode: 375932

CODE: (A500) New Use; Non-Food, Indoor FIFRA Sec. 2(MM) Uses

DATE DUE: 9/21/2010

FROM: Earl Goad, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Samsung Electronics Co.,LTD

*Earl Goad* 7/21/2010

*Karen Hicks*

PRODUCT FORMULATION FROM LABEL:

<u>PC Codes</u>	<u>Active Ingredient(s):</u>	<u>Weight (grams)</u>
072501	*Silver, elemental (purity not less than 99.9%)	10.8

\*Elemental Silver Electrodes –as a source material in this washing machine to produce electrolytically generated silver ions.”

## BACKGROUND:

The registrant has submitted this as a resubmission in response to an Agency letter, received January 13, 2010. This product is a silver electrode which is fixed within an assembly that is already installed into the washing machine. The electrode releases silver ions during a special washer rinse cycle that is designed to control odor-causing bacteria on washed fabrics and in the washer drum and washer water system.

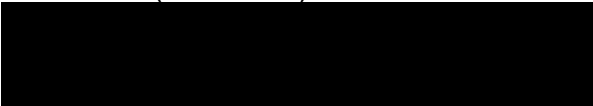
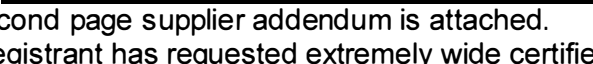
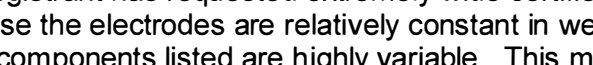
The data package included:

- Transmittal letter dated February 16, 2010 (Volume A):
- Confidential Statement of Formula (CSF) for the basic formulation (dated February 16, 2010). This is a CSF for the entire washing machine including the silver assembly which is a separate EPA File Symbol 82544-E.
- Product Chemistry Group A Data
  - Volume D (MRID# 479801-01) including guideline studies: 830.1800 Enforcement Analytical Method...
- Product Label for Silver Assembly with Washing Machine including the referenced Washing Machine User Manual

The product is produced by an integrated formulation system in that the electrode contains an active ingredient (silver) that is not provided from an EPA-registered product.

FINDINGS: See additional comments regarding each of these in the Product Chemistry Review section below prepared by EPA Contractor CSC, which has been edited as necessary to be consistent with other scientific data and Agency guidelines. The items here summarize that review with additional comments.

These are findings for the CSF and Label as submitted with this and previous product chemistry reviews. CTT finds these, as previously submitted and tentatively accepted, to be less desirable than those proposed in the RECOMMENDATIONS section which follows.

1. Confidential Statement of Formula: The basic CSF dated February 16, 2010.
  - a. The first page provides a list of four components to the washing machine:
    - i. The silver (electrodes)
    - ii. 
    - iii. 
    - iv. 
  - b. A second page supplier addendum is attached.
  - c. The registrant has requested extremely wide certified limits. This is because the electrodes are relatively constant in weight however the other components listed are highly variable. This might be considered a reasonable request if the variability were much less. .

**\*Inert ingredient information may be entitled to confidential treatment\***

- d. It is noted that the requested nominal %w/w on the CSF wider limits do not provide any useful information to the description of the active ingredient. However, the weight of the Silver electrode and its purity are necessary.
  - e. The independent weight and % variation of the non-electrode components are independently descriptive and may be put on the CSF for informational purposes. Also, their source suppliers should appear on the CSF addendum.
2. Product Label: With the exception of the ingredients statement, information on the product label appears to be sufficient. Reference is made to an attached "Washing Machine User Manual" which contains disposal information, use instructions, description of the silver ionization process, some technical specifications such as electrical, water pressure and hardness specifications and optional product claims.

The ingredient statement on the label currently shows the % silver as metallic based on the % relative to the weight of the other washing machine components. The weights of these other washing machine components are highly variable and must not be used as part of a definition of the active ingredient content.

### 3. Product Chemistry Group A and B:

- a. Product Chemistry Group A: requirements have been met with the exception of

OPPTS 830.1800 Enforcement Analytical Method. The enforcement analytical method was cited for use from the method which was submitted for this Silver Assembly including the Washing Machine (MRID#479801-01).

- i. The method, while found to be acceptable for use with direct measurement for some of the potential impurities, it is not written to directly measure the purity of silver. It does not take into account should other impurities be present (other than those impurities measured) such as impurities which might inadvertently become incorporated into the material during fabrication and processing. Other such impurities (present but not analyzed) would over estimate the purity of silver by this method.
- ii. The method must be upgraded to include specific protocol changes as is necessary to measure silver and the content and purity of silver directly.
- iii. The existing measure discussions of analytic method to analyze for the impurities may remain. The means of calculating purity of the silver by subtraction must be removed.

- b. Group B requirements have been met with the exception of OPPTS 830.6317 (Storage Stability) requirements, results for a minimum of 1 year from a GLP-compliant storage stability study must be provided. The Agency recognizes that this study is pending. Please Note: The storage stability study must also include observations regarding the physical appearance of the silver plates, noting any signs of discoloration or corrosion under the storage conditions.

RECOMMENDATIONS: CTT recommends that the CSF and Product Label be changed to represent the amount of silver in the assembly or the washing machine by direct weight and purity. The weight of the other components of the assembly or washing machine components (which are subject to change and variation) are not a reasonable basis for the measurement of silver content.

1. The Confidential Statement of Formula: The following represents changes recommended as per the above statement.
  - a. The Silver on CSF Column #10 should have purity and column #13 a amount weight (10.8g) nominal weight will be  $10.8 \times \text{purity} = 10.789$  or 10.8g with upper and lower calculated based on EPA standard limits applied to the purity. The weight must be expressed as weight in grams "10.8g". If the purity drops significantly with a change of source these numbers will have to be amended to represent the appropriate range in purity.
  - b. The [REDACTED] and remainder of the washing machine without the electrode can be stated each as an informational line on the CSF to include references to their sources on the CSF addendum. The column #13a weight amount of each of these should be simply approximate (i.e. "approx. 9.1g" or "approx. 0.9g")
2. Product Label: Changes recommended for the Label follow.
  - a. The weight in grams of the elemental silver present in the electrode based on the purity of the silver and the weight of the electrode exclusive of any other materials used to affix the bare electrode to the assembly.
  - b. Total weight of the assembly is unnecessary for the ingredient statement except for any other labeling considerations such as transport, installation and etc.
  - c. CTT recommends that the silver in the ingredients statement be footnoted to include a statement such as "silver as a source for electrolytically generated silver ions."

Product Chemistry Group B: OPPTS 830.6317 Storage Stability. The one year storage stability is currently pending. However, CTT recommends that the Storage Stability study could be waived. There are no chemical changes that can take place in silver of that purity which would result in a loss of active ingredient over time.

CONCLUSION:

CTT recommends that the active ingredient (silver) on both the CSF and Label use the weight of the silver (10.8g) instead of the % active (as a percent of the total weight of the washing machine).

The Enforcement Analytical Method for this product must be re-written as discussed in FINDINGS 3 a. The analytical method must directly quantify the amount and purity of the active ingredient.

There is very little value to performing storage stability on the silver electrode in this product. CTT recommends that this requirement be waived.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

#### a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: \_\_\_\_\_

#### b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.

Yes [ ] No [ ]

*Note: The product is not intended for food use.*

#### c. Physical state of product:

*Solid*

#### d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [ ] No [ ]

*Note: Group B information was not reported for this submission.*

#### e. The NCs and CLs are acceptable.

Yes [X] No [ ]

*Note: Non-standard certified limits were proposed for the active ingredient, [REDACTED]. An explanation of the basis for the non-standard limits was provided (in MRID 479812-01, previously submitted to EPA). The explanation appears sound.*

#### f. Active ingredient(s)

	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
Silver	0.011	0.008	0.017

#### g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ] No [ ] Not applicable [X]

**\*Inert ingredient information may be entitled to confidential treatment\***

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- |  |         |        |
|--|---------|--------|
| • 10% or more of a petroleum distillate: | Yes [ ] | No [X] |
| • 1.0% or more of methyl alcohol:        | Yes [ ] | No [X] |
| • sodium nitrite at any level:           | Yes [ ] | No [X] |
| • a toxic List 1 inert at any level:     | Yes [ ] | No [X] |
| • arsenic in any form:                   | Yes [ ] | No [X] |

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

*Note: Results for a minimum of 1 year from a GLP-compliant storage stability study is currently pending.*

**Table A:**  
**Product Chemistry (830 Series, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	479812-01 (previously submitted to EPA)
830.1600 Description of Materials	A	479812-01 (previously submitted to EPA)
830.1620 Production Process <sup>2</sup>	A	479812-01 (previously submitted to EPA)
830.1650 Formulation Process <sup>3</sup>	NA	
830.1670 Formation of Impurities <sup>4</sup>	A	479812-01 (previously submitted to EPA)
830.1700 Preliminary Analysis <sup>5</sup>	A	479812-02 (previously submitted to EPA)
830.1750 Certified Limits <sup>6</sup>	N – Non-standard certified limits were proposed for the active ingredient, [REDACTED]. An explanation of the basis for the non-standard limits was provided. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	479812-01 (previously submitted to EPA)
830.1800 Analytical Method <sup>7</sup>	N – A copy of an ICP-AES method was provided for determining the concentration of lead, bismuth, copper, and iron in the product. Method must directly measure silver content/purity  Note: Silver content is then assessed by subtracting the total amounts of the impurities.	479801-01
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.



**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical_Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
Note: Information satisfying Group B product data requirements were not reported for this submission as the Group B information is the same as that for EPA Reg. No. 82544-E.			
830.6302 Color			
830.6303 Physical State			
830.6304 Odor			
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions			
830.6314 Oxidation/ Reduction; Chemical Incompatibility			
830.6315 Flammability/ Flame Extension			
830.6316 Explodability			
830.6317 Storage Stability	G	Pending – Testing is pending. consideration might be given to waive this requirement	Letter from applicant to EPA, dated February 16, 2010
830.6319 Miscibility <sup>1</sup>			
830.6320 Corrosion Characteristics			
830.6321 Dielectric Breakdown Voltage			
830.7000 pH <sup>2</sup>			
830.7050 UV/Visible Absorption			
830.7100 Viscosity			
830.7200 Melting Point/Melting Range			
830.7220 Boiling Point/Boiling Range			
830.7300 Density/Relative Density/Bulk Density			
830.7370 Dissociation Constants in Water			
830.7550/830.7560/830.7570 Partition Coefficient			
830.7840/830.7860 Water Solubility			
830.7950 Vapor Pressure			

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable);  
NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required);  
U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

June 21, 2010

DP BARCODE: D375428

MRID : 479812-00, 479812-01, 479812-02

SUBJECT: Silver Assembly with Washing Machine

REG. NO. OR FILE SYMBOL: 82544-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Silver

CAS number: 7440-22-4

TEST LAB: Keller and Heckman LLP

SUBMITTER: Samsung Electronics Co., LTD.

GUIDELINE: None

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 06/21/10

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency


Office of Pesticide Programs

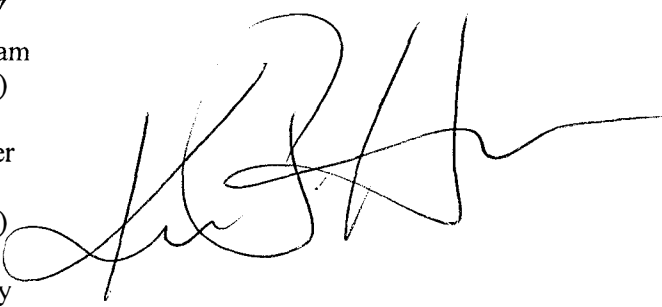
**Antimicrobials Division (AD)**

June 21, 2010

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 82544-R.

**From:** Juan F. Negrón, Chemist   
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) 

**To:** Marshall Swindell / Karen Leavy  
PM Team 33

**APPLICANT:** Samsung Electronics Co., LTD.

**Action code:** A500

**Due date:** 07/09/10

**Product Formulation from label**

**Active Ingredient(s)**

**% by wt.**

Silver ..... 0.006

**BACKGROUND:**

On behalf of the registrant, Samsung Electronics Co., LTD., has re-submitted an application for registration of a new end-use product, Silver Assembly with Washing Machine. [The resubmission is in response to an Agency letter, received January 13, 2010.] This product is a front-loading washing machine equipped with a factory-installed silver assembly that is designed to control odor-causing bacteria on washed fabrics and in the washer drum and washer water system. The Product Chemistry Reviewer has received the following documents:

- A letter, dated 02/16/10.
- Transmittal document, dated 02/16/10. MRID # 479812-00.
- Application for pesticide registration, dated 02/16/10.
- A label, dated 03/19/09, pin punched.
- Study titled "APPLICATION FOR PESTICIDE REGISTRATION Silver Assembly with Washing Machine." Volume "A," dated 02/11/10.
- Study titled "Product Identity and Composition" Volume "B" MRID 479812-01.
- Study titled "Preliminary Analysis" Volume "C," MRID 479812-02.
- Confidential Statements of Formula (CSFs), dated 03/05/09, 02/16/10 & 06/01/10, for the basic formulation.

**FINDINGS:**

1. The CSFs, dated 03/05/09, & 02/16/10, for the basic formulation is obsolete.
2. The CSF, dated 06/01/10, for the basic formulation is revised.
3. Except for the [REDACTED] none of the certified limits meet the EPA Standard Certified Limits.
4. Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.1800 (Analytical Method). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.
5. A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 479812-02. The study does not meet the requirements of 40 CFR Part 160. The study was conducted in the manufacturing research and quality control laboratory of the silver bar supplier; the laboratory has not established full recordkeeping requirements nor full written standard operating procedures required by 40 CFR Part 160.
6. Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability), and OPPTS 830.6320 (Corrosion Characteristics). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.
7. Information satisfying Group B product data requirements were not reported for this submission as the Group B information is the same as that for EPA Reg. No. 82544-E.

8. Information on the product label appears to be accurate and complete.
9. Non-standard certified limits were proposed for the active ingredient, [REDACTED]  
[REDACTED] An explanation of the basis for the non-standard limits was provided. The explanation appears sound. A signed certification statement was provided, as requested under OPPTS 830.1750(g).

#### **CONCLUSIONS:**

The CSF, dated 06/01/10, for the basic formulation is acceptable. The Agency needs the OPPTS 830.1800 Enforcement Analytical Method as part of the requirement. The OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) will be made available to the agency upon their completion.

#### **RECOMMENDATIONS:**

1. To satisfy OPPTS 830.1800 (Analytical Method) requirements, a copy of an analytical method suitable for enforcement purposes must be provided.
2. To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability study must be provided.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ]      No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: \_\_\_\_\_

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.  
Yes [ ]      No [ ]

*Note: The product is not intended for food use.*

c. Physical state of product:

*Solid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [ ]      No [ ]

*Note: Group B information was not reported for this submission.*

e. The NCs and CLs are acceptable.

Yes [X]      No [ ]

*Note: Non-standard certified limits were proposed for the active ingredient,*

[REDACTED] *An explanation of the basis for the non-standard limits was provided. The explanation appears sound.*

f. Active ingredient(s)

	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Silver	0.011	0.008	0.017

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes [ ]      No [ ]      Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ]      No [ ]      Not applicable [X]

## II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- |  |                              |  |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol:        | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level:           | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level:     | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form:                   | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

*Note: Results for a minimum of 1 year from a GLP-compliant storage stability study must be provided.*



**Table A:**  
**Product Chemistry (830 Series, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	479812-01
830.1600 Description of Materials	A	479812-01
830.1620 Production Process <sup>2</sup>	A	479812-01
830.1650 Formulation Process <sup>3</sup>	NA	
830.1670 Formation of Impurities <sup>4</sup>	A	479812-01
830.1700 Preliminary Analysis <sup>5</sup>	A	479812-02
830.1750 Certified Limits <sup>6</sup>	A	479812-02
830.1800 Analytical Method <sup>7</sup>	G – The method is being prepared and will be provided to EPA.	
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B: Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
Note: Information satisfying Group B product data requirements were not reported for this submission as the Group B information is the same as that for EPA Reg. No. 82544-E.			
830.6302 Color			
830.6303 Physical State			
830.6304 Odor			
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions			
830.6314 Oxidation/ Reduction; Chemical Incompatibility			
830.6315 Flammability/ Flame Extension			
830.6316 Explodability			
830.6317 Storage Stability	G	Pending – Testing is pending.	
830.6319 Miscibility <sup>1</sup>			
830.6320 Corrosion Characteristics	G	Pending – Testing is pending.	
830.6321 Dielectric Breakdown Voltage			
830.7000 pH <sup>2</sup>			
830.7050 UV/Visible Absorption			
830.7100 Viscosity			
830.7200 Melting Point/Melting Range			
830.7220 Boiling Point/Boiling Range			
830.7300 Density/Relative Density/Bulk Density			
830.7370 Dissociation Constants in Water			
830.7550/830.7560/830.7570 Partition Coefficient			
830.7840/830.7860 Water Solubility			
830.7950 Vapor Pressure			

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate. \* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C. <sup>1</sup>If product is an emulsifiable liquid <sup>2</sup>If product is dispersible with water



ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

December 2, 2009

**MEMORANDUM**

**SUBJECT:** Environmental Fate Assessment for Silver in Washing Machines and Review of Washing Machine Discharge Study

**Cas No.:** 7440-22-4      **DP Barcode(s):** D364888

**FROM:** James Breithaupt, Agronomist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**TO:** **Dennis Edwards, Chief, RMB 1**  
**Marshall Swindell, Risk Manager**  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**THRU:** Richard C. Petrie, Leader, Team Three  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

Norman Cook, Branch Chief  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

<b><u>Chemical Name</u></b>	<b><u>PC Code</u></b>	<b><u>CAS#</u></b>	<b><u>Common Name</u></b>
Silver	072501	7440-22-4	Silver

This memorandum contains the environmental fate assessment for silver used in the final rinse in washing machines. It also contains the DER for MRID 47708909 and the response to waivers in MRID 47707808.

**EXECUTIVE SUMMARY**

Samsung (the registrant) has submitted non-guideline environmental fate data on the discharge from washing machines with the silver release option in the final rinse cycle (47708909). They have also requested waivers other data in MRID 47708908. The study on discharge from

washing machines is unacceptable because of numerous study issues, including calculations that cannot be reproduced, lack of analytical data, and lack of controls. The data that are still required include solubility studies at various pH values from either guideline studies or acceptable literature and modified activated sludge respiration inhibition (850.6800).

## PRODUCT CHEMISTRY (from September 13, 2007 memo)

Table 1 below contains the chemical and physical properties of silver. As a metal, silver is not prone to chemical and microbial degradation per se, but will react with negatively-charged chemical species in soil and water to form complexes.

Table 1. Physical chemical properties of Silver

Parameter	Value	Comment
Molecular Weight (g/mol)	107.87	
Molecular Formula	Ag	
Water solubility (mg/L)	0.0004	At 25°C
Vapor Pressure/volatility (mmHg)	0	At 25°C
Henry's Law Constant (atm-m <sup>3</sup> /mol)	2.45 x 10 <sup>-002</sup>	At 25°C
pKa	Not provided	
Log K <sub>ow</sub> (octanol-water partition coefficient)	0.23	
K <sub>oc</sub> (organic carbon ratio in soil)	14.3	
K <sub>d</sub>	Not provided	
Mobility	Not provided	
BCF	3.162	

## ENVIRONMENTAL CHEMISTRY, FATE, AND TRANSPORT (from September 13, 2007 memo)

Silver (CAS 7440-22-4) is the metal with the highest thermal and electrical conductivity. It occurs both as native metal and as distinct mineral phases, mostly as sulfide minerals in complex ores such as proustite (Ag<sub>3</sub>AsS<sub>3</sub>) from where it is mined, processed (primarily by froth flotation), and then refined. Other minerals containing silver include cerargyrite (AgCl), pyrargyrite, and stephanite. The relative abundance of silver in the earth's crust is about 0.08 to 0.2 ppm.

The production and use of silver compounds as batteries (Ag<sub>2</sub>O), catalysts (AgNO<sub>3</sub>, AgCO<sub>3</sub>, AgClO<sub>4</sub>), medical preparations (AgCl), electroplating (AgCN), and photography (silver halides) may result in their release to the environment through various waste streams.

Although silver is, in general, not prone to atmospheric and ordinary oxidation and is resistant to corrosion by weak acids, the presence of sulfur-containing gases in the atmosphere and of sulfide ions in waters can tarnish the surface of silver. Strong, concentrated oxidizing acid solutions can dissolve silver, producing silver(I) species in solution; in alkaline solutions, silver is generally stable. Silver(I) forms soluble complexes with halide anions and with cyanide.

Chloride and bromide ions can react with surface silver oxides to form complexes that are more soluble than the oxides.

The oxidation states of I, II, and III have been identified in silver compounds, but when released to water, the only oxidation state is silver(I). The extent of oxidation (corrosion) of silver metal in aqueous environments is thus determined by the pH, the redox potential, and the temperature of the media. The type and concentration of soluble silver(I) that can form in aqueous media are determined by the nature and concentration of complexing anions present in the media. The formation of insoluble phases, such as silver sulfides, is also determined by the chemical characteristics of the aqueous media.

Silver(I) can readily react with sulfide ions and organic materials bearing thiol groups. Silver sulfides are insoluble, and in sulfide-rich natural waters, the formation of insoluble sulfides serves to immobilize silver. Thiol groups in aquatic sediments also contribute to the removal of silver(I) from the aqueous phase. However, in recent years it has been speculated that the transport and re-deposition of silver in the environment may involve formation of polysulfide silver species.

The speciation of  $\text{Ag}^+$  ions in fresh and marine waters is affected by the concentration of  $\text{Cl}^-$ . In seawater, silver is dominated by the anionic chloro-complex,  $[\text{AgCl}_3]^{-2}$ . In river water, levels of  $\text{AgSH}$  complexes are higher than both  $\text{Ag}^+$  and  $\text{AgCl}$ . The  $K_d$  values for silver suggest that these compounds will have a range of adsorption affinities to suspended solids and sediment. Relatively large amounts of organic colloids will lower the  $K_d$  of silver and remobilize it into the water column. Thus silver contaminated sediments may become a source of dissolved silver to overlying waters due to the remobilization of silver from particulate to dissolved phases. Silver compounds are expected to exist as ions in the environment and therefore volatilization from water surfaces is not expected to be an important fate process. Hydroxide complexes of silver occur at very low concentrations. Inorganic silver ion species will not bioconcentrate in aquatic organisms.

When released to air, silver compounds are expected to exist solely in the particulate phase in the ambient atmosphere. Particulate-phase silver will be removed from the atmosphere by wet and dry deposition.

When released to soil, silver will exist as  $\text{Ag}^+$  ions or as insoluble silver complexes. The partition coefficient ( $K_d$ ) for silver ranges from 16 to 1,300,000, which suggests that silver compounds have a range of mobility. Partitioning of silver compounds are primarily controlled by their speciation both in solution and on soils. Relatively large amounts of organic colloids will lower the  $K_d$  of silver compounds and remobilize the adsorbed silver compounds. Volatilization of silver compounds from moist soil surfaces is not expected to be an important fate process because silver compounds are expected to exist as ions which do not volatilize. Silver compounds are not expected to volatilize from dry soil surfaces based upon their ionic character and low vapor pressures of the non-ionizing compounds.

The germicidal properties of silver metal and silver compounds (such as oxides and salts) have long been recognized. The lethal effect of silver towards microorganisms and other lower life forms, the so-called “oligodynamic effect” is high and second to that of copper. The term “oligodynamic activity” is restricted to solutions in which the metal ion concentration is many orders of magnitude below what would be lethal to higher organisms. Silver-resistant bacteria have been found in urban and industrial polluted sites. It is believed that the resistance to silver is determined by genes on plasmids. The lower affinity of the cells for silver(I) is related to the tendency of silver(I) to be more effectively complexed with extracellular halides, thiols, or organic compounds.

### **Status of Environmental Fate Data Requirements**

The registrant is requesting waivers for a wide range of studies in MRID 47707808. These included:

- Hydrolysis (835.2120)
- Photodegradation in water (835.2240)
- Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)
- Modified Activated Sludge, Respiration Inhibition Test (850.6800)
- Porous Pot Study(835.3220)
- Leaching and Adsorption-Desorption (835.1230 and 835.1240)
- Dissipation in Aquatic Sediment (835.6200) and Monitoring of Representative U.S. Waters (no guideline)
- Metabolism Studies
  - Aerobic Soil Metabolism (835.4100)
  - Anaerobic Aquatic Metabolism (835.4200)
  - Aerobic Aquatic Metabolism (835.4300)
  - Anaerobic Aquatic Metabolism (835.4400)

**Hydrolysis (161-1, 835.2120, Required) - Give Jim CAS - lookup Groos memo - In H<sub>2</sub>O solubility -**

The September 13, 2007 memorandum stated that hydrolysis data can be waived if the registrant would submit solubility studies at various pH values from either guideline studies or from acceptable literature. RASSB is unaware of any solubility data being submitted to satisfy this requirement, and therefore, data are still required.

### **Photodegradation in Water (161-2, 835.2240, Waived)**

The photodegradation in water data requirement is waived because silver is a metal and will not degrade by light, either directly or indirectly.

**Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)  
[Waived]**

These data can be waived because the literature clearly indicates that sorption to sludge and reaction to form insoluble sulfide and thiosulfate complexes are the primary routes of dissipation in wastewater treatment plants. Also, silver is not likely to biodegrade because it is a metal.

**Modified Activated Sludge Respiration Inhibition Test (850.6800)**

These data can be waived because there is a December 1987 Office of Water document with reporting thresholds of 0.25 mg/L and 0.25-5 mg/l inhibition threshold concentration.

**Porous Pot Test (835.3220, Waived)**

This study is not required because the proposed use is indoor, non-food.

**Leaching-Adsorption-Desorption (163-1, 835.1230 and 835.1240, Waived)**

Silver will exist primarily as complexes and most ions will be associated with soil or sediment because of the positive charge of silver and the negative charge of soil.

**Metablism studies (835.4100, 835.4200, 835.4300, 835.4400, Waived)**

All metabolism studies in soil can be waived for silver because silver is an inorganic ion or complex that will not degrade. These test data requirements relate to organic compounds that have the potential to mineralize.

**Aquatic Field Dissipation (835.6200, Waived)**

Data on aquatic field dissipation can be waived because silver is an inorganic ion or complex that will not degrade.

**Monitoring of Representative U.S. Waters (no guideline, Waived)**

This data requirement can be waived because silver is a naturally occurring metal that is often found as a complex with negatively-charged ions. There is a National Secondary Drinking Water Regulation of 0.1 mg/L or less for silver.

The DER for MRID 47707809 is attached to this memorandum. If there are any questions, please contact Jim Breithaupt at 703-305-5925 or at [breithaupt.james@epa.gov](mailto:breithaupt.james@epa.gov).

Sign-off Date : 12/02/09  
DP Barcode No. : D364888




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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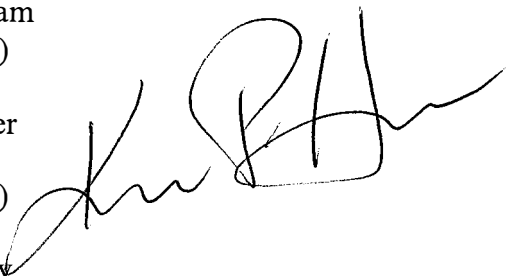
OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

December 23, 2009

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 82544-R.

**From:** Juan F. Negrón, Chemist   
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) 

**To:** Marshall Swindell / Karen Leavy  
PM Team 33

**Applicant:** Samsung Electronics Co., LTD.

**Action code:** A500

**Due date:** 01/09/10

**Product Formulation**

**Active Ingredient(s):**

	% by wt.
Silver	0.006



## BACKGROUND:

On behalf of the registrant, Samsung Electronics Co., LTD., the consultant, Keller and Heckman LLP, responded to the Agency letter to update deficiencies from the previous product chemistry review. This product is a front-loading washing machine equipped with a factory-installed “Silver Assembly” that is designed to control odor-causing bacteria on washed fabrics and in the washer drum and washer water system. The Product Chemistry Reviewer has received the following documents:

- 830 Group B guidelines, dated 11/05/09.
- A letter, dated 11/05/09.
- A label, undated.
- ICP method for the measurement of silver purity.
- Preliminary analysis.

## FINDINGS:

1. The total weight is blank in box 17 of the CSF for the basic formulation. No updated CSF has been received at this time.
2. Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS (830.1700 Preliminary Analysis), and OPPTS 830.1800 (Analytical Method). See the “Recommendations” section of this report for deficiencies. See also Table A of this report.
3. A preliminary analysis was conducted for five lots. See the following results:  
Silver (raw material) → [99.9954, 99.9956, 99.9955, 99.9955, and 99.9958] % with an average of 99.9956%.
4. The registrant submitted a method for the measurement of silver purity that is contained on one page and does not satisfy the OPPTS 830.1800 (Analytical Method). See the “Recommendations” section of this report for deficiencies.
5. The registrant has indicated that the OPPTS 830.1800 Enforcement Analytical Method is the ICP Method. However, no copy of the method has been provided.
6. Group B product chemistry data requirements applicable to end-use products have been met with the exception of the 830.6317 storage stability guideline. The 830 group B guidelines that the registrant submitted for this review are for those guidelines that are not required because the product is an end-use product.

7. The 830 Group B guidelines were not reported for this submission since the group B will be the same from 82544-E. The 82544-R is the silver assembly with washing machine.
8. Certain information on the product label could be improved, as noted in the “Recommendations” section of this report. The registrant did not submit an updated label at this time.

## **CONCLUSION:**

The preliminary analysis is partially acceptable. The preliminary analysis must be conducted on the product and not the raw material. This product shows that silver is 0.006% as claimed on the label. Therefore, the preliminary must show assays that show the concentration of silver as per label. The OPPTS 830.1800 (Enforcement Analytical Method) is not acceptable.

The Agency must receive the results of a one year storage stability study.

## **RECOMMENDATIONS:**

1. The registrant must indicate the total weight of [REDACTED] in the CSF for the basic formulation.
2. The preliminary analysis must be based on the product, **Silver Assembly with Washing Machine**. The preliminary analysis must be based on the product as per label.
3. To satisfy OPPTS 830.1800 (Analytical Method) requirements, a copy of an analytical method suitable for enforcement purposes must be provided for the active ingredient (i.e., silver). This method must be formatted and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, Limit of detection (LOD), limit of Quantification (LOQ), and Calculations. A reference to “ICP Method” is not sufficient.
4. The following revision to the product label is recommended:
  - Under the “Disposal” section of the product label, identify disposal options for the container using the following (or similar text): “Place in trash or offer for recycling, if available.” *(These deficiencies were observed from the past review and the registrant has not responded at this time).*



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

December 23, 2009

DP BARCODE: D372197

MRID :

SUBJECT: Silver Assembly

REG. NO. OR FILE SYMBOL: 82544-E

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Silver (072501)

CAS Number: (7440-22-4)

TEST LAB: N/A

SUBMITTER: Samsung Electronics Co., LTD.

GUIDELINE: 830 Groups "A & B"

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 12/23/09

COMMENT:

# DATA PACKAGE BEAN SHEET

Date: 14-Dec-2009

Page 1 of 1

Decision #: 407607

DP #: (372196)

PRIA

Parent DP #:

Submission #: 846940

## \*\*\* Registration Information \*\*\*

Registration: 82544-R - SILVER ASSEMBLY WITH WASHING MACHINE

Company: 82544 - SAMSUNG ELECTRONICS CO., LTD.

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: Calculated Due Date: 09-Jan-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A500) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients:

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Dec-2009

Due Back:

DP Ingredient:

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

### Assigned To

### Date In

### Date Out

Organization: AD / PSB

12/15/09

Last Possible Science Due Date: 20-Oct-2009

Team Name: CTT

12/23/09

Science Due Date: 6/8/09

Reviewer Name: Juan Negrón

12/15/09

12/23/09

Sub Data Package Due Date: 6/22/09

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

Please review the submitted Chemistry data/information to clarify the data deficiencies; PRIA, Action Code A500

## MEMORANDUM

TO: Juan Negron

FROM: Cathy Rice  
Scientist

DATE: November 5, 2009

RE: Samsung (EPA File Symbol 82544-R and 82544-E)

---

We are responding to your October 16, 2009 telephone inquiring regarding the two Samsung products listed above. The requested information follows:

### Product Chemistry – Group B Data Requirements

Guideline	Description	Result
830.6302	Color	NR because the products is an end-use product
830.6304	Odor	NR because the products is an end-use product
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	NR because the products is an end-use product
830.7050	UV/Visible absorption	NR because the products is an end-use product
830.7200	Melting point/melting range	NR because the products is an end-use product
830.7220	Boiling point/boiling range	NR because the products is an end-use product
830.7370	Dissociation constant	NR because the products is an end-use product
830.7520	Particle size, fiber length, and diameter distribution	NR because the products is an end-use product
830.7550	Petition coefficient coefficient (n-octanol/ water), shake flask method	NR because the products is an end-use product
830.7560	Petition coefficient coefficient (n-octanol/	NR because the products is an end-use product

Guideline	Description	Result
	water), generator column method	
830.7570	Petition coefficient (n-octanol/ water), estimation by liquid chromatography	NR because the products is an end-use product
830.7840	Water solubility; column elution method; shake flask method	NR because the products is an end-use product
830.7860	Water solubility; column elution method; generator column method	NR because the products is an end-use product
830.7950	Vapor Pressure	NR because the products is an end-use product

### Preliminary Analysis

The preliminary analysis is presented in Volume 3 (MRID 477078-02) of washing machine original submission. Below is summary of this information:

Metal Analyzed	Result					Average
	11/14/08	11/17/08	12/1/08	12/4/08	12/4/08	
Lot No.	8B-1176	8B-1121	8B-1164	8B-1180	8B-1179	
Ag	Remainder >99.9954	Remainder >99.9956	Remainder >99.9955	Remainder >99.9955	Remainder >99.9958	>99.9956
Pb	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Bi	0.0002	0.0003	0.0004	0.0003	0.0005	0.0003
Cu	0.0021	0.0019	0.0017	0.0019	0.0016	0.0018
Fe	0.0013	0.0012	0.0014	0.0013	0.0011	0.0013

\* K S D – Korean Standard D 1710



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

December 23, 2009

DP BARCODE: D372196

MRID :

SUBJECT: Silver Assembly with Washing Machine

REG. NO. OR FILE SYMBOL: 82544-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Silver (072501)

CAS Number: (7440-22-4)

TEST LAB: N/A

SUBMITTER: Samsung Electronics Co., LTD.

GUIDELINE: 830 Groups "A & B"

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 12/23/09

COMMENT:




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

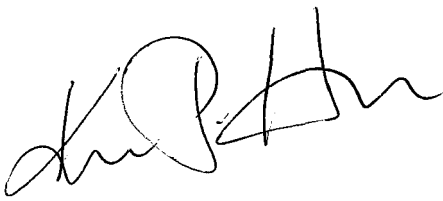
OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

December 23, 2009

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 82544-E.

**From:** Juan F. Negrón, Chemist   
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) 

**To:** Marshall Swindell / Karen Leavy  
PM Team 33

**Applicant:** Samsung Electronics Co., LTD.

**Action code:** A500.1

**Due date:** 01/09/10

**Product Formulation**

**Active Ingredient(s):**

Silver

% by wt.  
25.9



## BACKGROUND:

On behalf of the registrant, Samsung Electronics Co., LTD., the consultant, Keller and Heckman LLP, responded to the Agency letter to update deficiencies from the previous product chemistry review. This product is a washing machine component, designed to control odor-causing bacteria on washed fabrics and in the washer drum and washer water system. This product is a replacement part to the product, Silver Assembly with Washing Machine, which is pending registration (See 82544-R, DP# 364188). The product is produced by an integrated formulation system. The Product Chemistry Reviewer has received the following documents:

- 830 Group B guidelines, dated 11/05/09.
- A letter, dated 11/05/09.
- A label, undated.
- ICP method for the measurement of silver purity.
- Preliminary analysis.

## FINDINGS:

1. A preliminary analysis was conducted for five lots. See the following results:  
Silver (raw material) → [99.9954, 99.9956, 99.9955, 99.9955, and 99.9958] % with an average of 99.9956%.
2. The registrant submitted a method for the measurement of silver purity that is contained on one page and does not satisfy the OPPTS 830.1800 (Analytical Method). See the “Recommendations” section of this report for deficiencies.
3. The registrant has indicated that the OPPTS 830.1800 Enforcement Analytical Method is the ICP Method. However, no copy of the method has been provided.
4. Group B product chemistry data requirements applicable to end-use products have been met with the exception of the 830.6317 storage stability guideline. The 830 group B guidelines that the registrant submitted for this review are for those guidelines that are not required because the product is an end-use product.
5. Certain information on the product label could be improved, as noted in the “Recommendations” section of this report. The registrant did not submit an updated label at this time.

## CONCLUSION:

The preliminary analysis is partially acceptable. The preliminary analysis must be conducted on the product and not the raw material. This product shows that silver is 25.9% as claimed on the label. Therefore, the preliminary must show assays that show the concentration of silver as per label. The OPPTS 830.1800 (Enforcement Analytical Method) is not acceptable.

The Agency must receive the results of a one year storage stability study.

## RECOMMENDATIONS:

1. The preliminary analysis must be based on the product as per label.
2. To satisfy OPPTS 830.1800 (Analytical Method) requirements, a copy of an analytical method suitable for enforcement purposes must be provided for the active ingredient (i.e., silver). This method must be formatted and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, and Calculations. A reference to “ICP Method” is not sufficient.
3. The following revisions to the product label are recommended: (*These deficiencies were observed from the past review and the registrant has not responded at this time*).
  - Under the “Disposal” section of the product label, identify disposal options for the container using the following (or similar text): “Place in trash or offer for recycling, if available.”
  - Under the “Directions for Use” section of the product label, change “can only be installed by authorized repair technicians” to read “must be installed by an authorized repair technician.”
  - Under the “Replacement directions” section of the product label, change “washing machining” to read “washing machine.”
  - Under the “Replacement directions” section of the product label, change “assemble the Top Cover” to read “reattach the Top Cover.”

5. Sodium Hypochlorite (new and foreign sources) and anything outside of the standard solutions: Group A and B data required
6. Sodium Hypochlorite (registered source at the beginning) (non standard range of solutions) ----- end product is an unregistered source: Group A and B Data is required
7. Sodium Hypochlorite (registered source at the beginning) (standard range of solutions) ----end product is unregistered source : only certificate of analysis is required
8. Standard range is 5.25 - 12.5)
9. Zero Limits - No zero limits are allowed - must have the exact same range for each inert concentration
10. Color ID - registrant identify specific color
11. When the alternate formulation is color specific, there must be a different alternate for each color.

# DATA PACKAGE BEAN SHEET

Date: 14-Dec-2009

Page 1 of 1

Decision #: 407861

DP #: (372197)

PRIA

Parent DP #:

Submission #: 846941

## \*\*\* Registration Information \*\*\*

Registration: **82544-E - SILVER ASSEMBLY**

Company: 82544 - SAMSUNG ELECTRONICS CO., LTD.

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: Calculated Due Date: 09-Jan-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A500.1) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients:

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Dec-2009

Due Back:

DP Ingredient:

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

### Assigned To

### Date In

### Date Out

Organization: AD / PSB

12/15/09

Last Possible Science Due Date: 20-Oct-2009

Team Name: CTT

12/23/09

Science Due Date: 6/8/10

Reviewer Name: Juan Negron

12/15/09

12/23/09

Sub Data Package Due Date: 6/22/10

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

Please review the submitted product chemistry data to clarify data deficiencies  
PRIA, Action Code A500.1

## MEMORANDUM

TO: Juan Negron

FROM: Cathy Rice  
Scientist

DATE: November 5, 2009

RE: Samsung (EPA File Symbol 82544-R and 82544-E)

---

We are responding to your October 16, 2009 telephone inquiring regarding the two Samsung products listed above. The requested information follows:

### Product Chemistry – Group B Data Requirements

Guideline	Description	Result
830.6302	Color	NR because the products is an end-use product
830.6304	Odor	NR because the products is an end-use product
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	NR because the products is an end-use product
830.7050	UV/Visible absorption	NR because the products is an end-use product
830.7200	Melting point/melting range	NR because the products is an end-use product
830.7220	Boiling point/boiling range	NR because the products is an end-use product
830.7370	Dissociation constant	NR because the products is an end-use product
830.7520	Particle size, fiber length, and diameter distribution	NR because the products is an end-use product
830.7550	Petition coefficient coefficient (n-octanol/water), shake flask method	NR because the products is an end-use product
830.7560	Petition coefficient coefficient (n-octanol/	NR because the products is an end-use product

Guideline	Description	Result
	water), generator column method	
830.7570	Petition coefficient (n-octanol/ water), estimation by liquid chromatography	NR because the products is an end-use product
830.7840	Water solubility; column elution method; shake flask method	NR because the products is an end-use product
830.7860	Water solubility; column elution method; generator column method	NR because the products is an end-use product
830.7950	Vapor Pressure	NR because the products is an end-use product

### Preliminary Analysis

The preliminary analysis is presented in Volume 3 (MRID 477078-02) of washing machine original submission. Below is summary of this information:

Metal Analyzed	Result					Average
	11/14/08	11/17/08	12/1/08	12/4/08	12/4/08	
Lot No.	8B-1176	8B-1121	8B-1164	8B-1180	8B-1179	
Ag	Remainder >99.9954	Remainder >99.9956	Remainder >99.9955	Remainder >99.9955	Remainder >99.9958	>99.9956
Pb	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Bi	0.0002	0.0003	0.0004	0.0003	0.0005	0.0003
Cu	0.0021	0.0019	0.0017	0.0019	0.0016	0.0018
Fe	0.0013	0.0012	0.0014	0.0013	0.0011	0.0013

\* KS D – Korean Standard D 1710

### **ICP method for the measurement of silver purity**

The method for measurement of silver purity, KS D1701, was summarized and translated into English.

Original test method: KS D 1701 (Method for chemical analysis of silver bullion)

#### **Test Conditions and Methods**

1. Pre-treatment for the measurement of lead impurity
  - a. Take 10g of silver bar and put in 300mL-beaker.
  - b. Add 4mL of nitric acid (1:1), put glass dish to cover the beaker and heat until it boils.
  - c. Leave it in room temperature, wash the surface of the glass dish with water and add water to the beaker to make the total volume to 100mL.
  - d. Add 5mL of Ferrous ammonium sulfate and few drops of ammonia while stirring the solution. Add another 20mL of ammonia after  $\text{Fe}(\text{OH})_2$  precipitate. And add approximately 5g of ammonium carbonate for 10 minutes and leave it at 60~80°C for 30 minutes.
  - e. After removing the cover glass, filter the solid parts from the beaker and wash with warm ammonia for several times, and mix the filtered solution and the washed solution.
  - f. Wash the solid part on the filter paper with warm water, wash the filter with warm hydrochloric acid (1:50) several times and collect all the liquid in the same beaker. Heat the beaker and concentrate the solution until the volume of the solution to 10mL. Transfer the solution to 100mL beaker and heat until all liquid part is evaporated.
  - g. Once the beaker is cooled in the room temperature, add 5mL of hydrochloric acid (1:2) and heat until the solid is dissolved. Cool the solution to room temperature and transfer the solution to 25mL volumetric flask and add water to fill the flask.
2. Pre-treatment methods for Bi (Bismuth), Cu (copper) and Fe (iron) are not translated in this document.
3. The concentration of the impurities for Pb, Bi, Cu and Fe can be measured using ICP-AES and ICP-MS.

The original file can be purchased at Korean Standard Information Center at;  
<http://www.standard.go.kr/>



Re: This is for Chemistry / suggest1

Juan Negron to: Karen Hicks

01/13/2010 12:32 PM

Cc: blackwell.ian, Emily Mitchell, goad.earl, jiang.chris, johnson.leon,  
negron.juan, Salvador Rodriguez, traska.alexander, Wallace Powell



Good morning! what you are about to see is a draft. I think that we should approach CTT policy as follow:

#### I. New commonly used chemical registration

A. For integrated system - means that the source of the active ingredient is unregistered.

Requirements - 830 Group A & B guidelines [including 5 batches of analysis(830.1700) along with the certificate of analysis of the raw material and discussion of formation of impurities (830.1670)]

Special scenario

Case 1 - If the submission is a Me-too and the product is similar to a registered product - Group "B" can be waived.

Case 2 - If the product is not a Me-too but the product is similar to a registered product - Group "B" can be waived.

Case 3 - If the product contains a registered source and the active ingredient change to another active ingredient because of a chemical reaction, then Group A & B is required [including 5 batches of analysis(830.1700) along with the certificate of analysis of the raw material and discussion of formation of impurities (830.1670)].

B. For non-integrated system -

Requirements - 830 Group A & B guidelines. From Group A the registrant does not required to provide 830.1670 & 830.1700 guidelines.

Special scenario

Case 1 - If the submission is a Me-too and the product is similar to a registered product - Group "B" can be waived.

Case 2 - If the product is not a Me-too but the product is similar to a registered product - Group "B" can be waived.

#### II. Sodium and Calcium hypochlorite salts

Using the guidance for the reregistrations of pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA sec. 3 (g)). The active ingredient as the sole in the product. The product must match one of the concentration stated in "section E. Acceptable Ranges and Limits."

A. For non-integrated system -

Requirements - 830 Group A [830.1670, 830.1700 & 830.1800 are waived]. Group B is waived.

Case 1 - If the product contains a registered source and the active ingredient change to another active ingredient because of a chemical reaction, then Group A & B is required [including 5 batches of analysis(830.1700) along with the certificate of analysis of the raw material and discussion of formation of impurities (830.1670)].

B. For integrated system -

Requirements - 830 Group A [including 5 batches of analysis(830.1700) along with the certificate of analysis of the raw material. Group B is waived.

Case 1 - If the product contains a registered source and the active ingredient change to another active ingredient because of a chemical reaction, then Group A & B is required [including 5 batches of analysis(830.1700) along with the certificate of analysis of the raw material and discussion of formation of impurities (830.1670)].

C. For those product that are not under the guidance mentioned above - The requirements are to



be follow in the same way as in section I "New commonly used chemical registration."

### III. Zero Limits

No zero limits are allowed - Calculation in column 14 of the CSF must be shown by either:

A. If the product is using the EPA Standard Certified Limits or

B. If the product is using a wider certified limits - a justification letter for wider certified limits is required.

C. If the product is using a list of dyes, fragrances, etc. then the CSF must have an attachment and should indicate "or." The certified limits must be shown by either using "A or B" mentioned above.

### IV. Color ID

A. For TGA1 and MUP the 830.6302 Color guideline must be meet.

B. For EUP the 830.6302 Color guideline is waived.

C. For product paints -

- The basic formulation and alternates formulation must be identify by a color. Each color might have more than one supplier in which case the CSF must have an attachment to list all the suppliers.

They might be more scenarios but we can added later on, and other reviewers can add other scenario. For any concern please let me know.

U.S. Environmental Protection Agency  
Antimicrobials Division  
Attn. Juan F. Negrón  
Room: S-8848  
Phone # 703-308-8116  
Fax # 703-308-8481  
Mail Code 7510P  
2777 South Crystal Drive  
Arlington, VA 22202

Karen Hicks

Please send your comments to me for the followi...

01/12/2010 11:42:20 PM

From: Karen Hicks/DC/USEPA/US  
To: blackwell.ian@epa.gov, johnson.leon@epa.gov, goad.earl@epa.gov, jiang.chris@epa.gov, traska.alexander@epa.gov, negron.juan@epa.gov, Salvador Rodriguez/DC/USEPA/US@EPA, Wallace Powell/DC/USEPA/US@EPA  
Cc: Emily Mitchell/DC/USEPA/US@EPA  
Date: 01/12/2010 11:42 PM  
Subject: This is for Chemistry

---

Please send your comments to me for the following by close of business Friday, Jan. 15, 2010. If you have something to add that is not represented here...please send me an additional number. If you have a comment to add to what is already here, please add to the number listed. I will compile all comments and send back to you next week for a final correction.

1. If a product is considered to be a commonly used chemical and is not registered: The 5 batch analysis and Group A data is required
2. If a product is considered to be a commonly used chemical and is not registered (but it is a public health product): The 5 batch analysis, Group A data and Storage Stability and Corrosion Characteristics are required.
3. Sodium Hypochlorite (registered source) - 4 standard solutions : no generic data is needed: only certificate of analysis is required
4. Sodium Hypochlorite (unregistered source) - 4 standard solutions : Group A and B data required



ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

December 2, 2009

**MEMORANDUM**

**SUBJECT:** Environmental Fate Assessment for Silver in Washing Machines and Review of Washing Machine Discharge Study

**Cas No.:** 7440-22-4      **DP Barcode(s):** D364888

**FROM:** James Breithaupt, Agronomist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

**TO:** **Dennis Edwards, Chief, RMB 1**  
**Marshall Swindell, Risk Manager**  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**THRU:** Richard C. Petrie, Leader, Team Three  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

Norman Cook, Branch Chief  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

<b><u>Chemical Name</u></b>	<b><u>PC Code</u></b>	<b><u>CAS#</u></b>	<b><u>Common Name</u></b>
Silver	072501	7440-22-4	Silver

This memorandum contains the environmental fate assessment for silver used in the final rinse in washing machines. It also contains the DER for MRID 47708909 and the response to waivers in MRID 47707808.

**EXECUTIVE SUMMARY**

Samsung (the registrant) has submitted non-guideline environmental fate data on the discharge from washing machines with the silver release option in the final rinse cycle (47708909). They have also requested waivers other data in MRID 47708908. The study on discharge from

washing machines is unacceptable because of numerous study issues, including calculations that cannot be reproduced, lack of analytical data, and lack of controls. The data that are still required include solubility studies at various pH values from either guideline studies or acceptable literature and modified activated sludge respiration inhibition (850.6800).

## PRODUCT CHEMISTRY (from September 13, 2007 memo)

Table 1 below contains the chemical and physical properties of silver. As a metal, silver is not prone to chemical and microbial degradation per se, but will react with negatively-charged chemical species in soil and water to form complexes.

Table 1. Physical chemical properties of Silver

Parameter	Value	Comment
Molecular Weight (g/mol)	107.87	
Molecular Formula	Ag	
Water solubility (mg/L)	0.0004	At 25°C
Vapor Pressure/volatility (mmHg)	0	At 25°C
Henry's Law Constant (atm-m <sup>3</sup> /mol)	2.45 x 10 <sup>-002</sup>	At 25°C
pKa	Not provided	
Log K <sub>ow</sub> (octanol-water partition coefficient)	0.23	
K <sub>oc</sub> (organic carbon ratio in soil)	14.3	
K <sub>d</sub>	Not provided	
Mobility	Not provided	
BCF	3.162	

## ENVIRONMENTAL CHEMISTRY, FATE, AND TRANSPORT (from September 13, 2007 memo)

Silver (CAS 7440-22-4) is the metal with the highest thermal and electrical conductivity. It occurs both as native metal and as distinct mineral phases, mostly as sulfide minerals in complex ores such as proustite (Ag<sub>3</sub>AsS<sub>3</sub>) from where it is mined, processed (primarily by froth flotation), and then refined. Other minerals containing silver include cerargyrite (AgCl), pyrargyrite, and stephanite. The relative abundance of silver in the earth's crust is about 0.08 to 0.2 ppm.

The production and use of silver compounds as batteries (Ag<sub>2</sub>O), catalysts (AgNO<sub>3</sub>, AgCO<sub>3</sub>, AgClO<sub>4</sub>), medical preparations (AgCl), electroplating (AgCN), and photography (silver halides) may result in their release to the environment through various waste streams.

Although silver is, in general, not prone to atmospheric and ordinary oxidation and is resistant to corrosion by weak acids, the presence of sulfur-containing gases in the atmosphere and of sulfide ions in waters can tarnish the surface of silver. Strong, concentrated oxidizing acid solutions can dissolve silver, producing silver(I) species in solution; in alkaline solutions, silver is generally stable. Silver(I) forms soluble complexes with halide anions and with cyanide.

Chloride and bromide ions can react with surface silver oxides to form complexes that are more soluble than the oxides.

The oxidation states of I, II, and III have been identified in silver compounds, but when released to water, the only oxidation state is silver(I). The extent of oxidation (corrosion) of silver metal in aqueous environments is thus determined by the pH, the redox potential, and the temperature of the media. The type and concentration of soluble silver(I) that can form in aqueous media are determined by the nature and concentration of complexing anions present in the media. The formation of insoluble phases, such as silver sulfides, is also determined by the chemical characteristics of the aqueous media.

Silver(I) can readily react with sulfide ions and organic materials bearing thiol groups. Silver sulfides are insoluble, and in sulfide-rich natural waters, the formation of insoluble sulfides serves to immobilize silver. Thiol groups in aquatic sediments also contribute to the removal of silver(I) from the aqueous phase. However, in recent years it has been speculated that the transport and re-deposition of silver in the environment may involve formation of polysulfide silver species.

The speciation of  $\text{Ag}^+$  ions in fresh and marine waters is affected by the concentration of  $\text{Cl}^-$ . In seawater, silver is dominated by the anionic chloro-complex,  $[\text{AgCl}_3]^{-2}$ . In river water, levels of  $\text{AgSH}$  complexes are higher than both  $\text{Ag}^+$  and  $\text{AgCl}$ . The  $K_d$  values for silver suggest that these compounds will have a range of adsorption affinities to suspended solids and sediment. Relatively large amounts of organic colloids will lower the  $K_d$  of silver and remobilize it into the water column. Thus silver contaminated sediments may become a source of dissolved silver to overlying waters due to the remobilization of silver from particulate to dissolved phases. Silver compounds are expected to exist as ions in the environment and therefore volatilization from water surfaces is not expected to be an important fate process. Hydroxide complexes of silver occur at very low concentrations. Inorganic silver ion species will not bioconcentrate in aquatic organisms.

When released to air, silver compounds are expected to exist solely in the particulate phase in the ambient atmosphere. Particulate-phase silver will be removed from the atmosphere by wet and dry deposition.

When released to soil, silver will exist as  $\text{Ag}^+$  ions or as insoluble silver complexes. The partition coefficient ( $K_d$ ) for silver ranges from 16 to 1,300,000, which suggests that silver compounds have a range of mobility. Partitioning of silver compounds are primarily controlled by their speciation both in solution and on soils. Relatively large amounts of organic colloids will lower the  $K_d$  of silver compounds and remobilize the adsorbed silver compounds. Volatilization of silver compounds from moist soil surfaces is not expected to be an important fate process because silver compounds are expected to exist as ions which do not volatilize. Silver compounds are not expected to volatilize from dry soil surfaces based upon their ionic character and low vapor pressures of the non-ionizing compounds.

The germicidal properties of silver metal and silver compounds (such as oxides and salts) have long been recognized. The lethal effect of silver towards microorganisms and other lower life forms, the so-called “oligodynamic effect” is high and second to that of copper. The term “oligodynamic activity” is restricted to solutions in which the metal ion concentration is many orders of magnitude below what would be lethal to higher organisms. Silver-resistant bacteria have been found in urban and industrial polluted sites. It is believed that the resistance to silver is determined by genes on plasmids. The lower affinity of the cells for silver(I) is related to the tendency of silver(I) to be more effectively complexed with extracellular halides, thiols, or organic compounds.

### **Status of Environmental Fate Data Requirements**

The registrant is requesting waivers for a wide range of studies in MRID 47707808. These included:

- Hydrolysis (835.2120)
- Photodegradation in water (835.2240)
- Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)
- Modified Activated Sludge, Respiration Inhibition Test (850.6800)
- Porous Pot Study(835.3220)
- Leaching and Adsorption-Desorption (835.1230 and 835.1240)
- Dissipation in Aquatic Sediment (835.6200) and Monitoring of Representative U.S. Waters (no guideline)
- Metabolism Studies
  - Aerobic Soil Metabolism (835.4100)
  - Anaerobic Aquatic Metabolism (835.4200)
  - Aerobic Aquatic Metabolism (835.4300)
  - Anaerobic Aquatic Metabolism (835.4400)

#### **Hydrolysis (161-1, 835.2120, Required)**

The September 13, 1007 memorandum stated that hydrolysis data can be waived if the registrant would submit solubility studies at various pH values from either guideline studies or from acceptable literature. RASSB is unaware of any solubility data being submitted to satisfy this requirement, and therefore, data are still required.

#### **Photodegradation in Water (161-2, 835.2240, Waived)**

The photodegradation in water data requirement is waived because silver is a metal and will not degrade by light, either directly or indirectly.

**Activated Sludge Sorption Isotherm (835.1110) and Ready Biodegradability (835.3110)  
[Waived]**

These data can be waived because the literature clearly indicates that sorption to sludge and reaction to form insoluble sulfide and thiosulfate complexes are the primary routes of dissipation in wastewater treatment plants. Also, silver is not likely to biodegrade because it is a metal.

**Modified Activated Sludge Respiration Inhibition Test (850.6800)**

These data can be waived because there is a December 1987 Office of Water document with reporting thresholds of 0.25 mg/L and 0.25-5 mg/l inhibition threshold concentration.

**Porous Pot Test (835.3220, Waived)**

This study is not required because the proposed use is indoor, non-food.

**Leaching-Adsorption-Desorption (163-1, 835.1230 and 835.1240, Waived)**

Silver will exist primarily as complexes and most ions will be associated with soil or sediment because of the positive charge of silver and the negative charge of soil.

**Metablism studies (835.4100, 835.4200, 835.4300, 835.4400, Waived)**

All metabolism studies in soil can be waived for silver because silver is an inorganic ion or complex that will not degrade. These test data requirements relate to organic compounds that have the potential to mineralize.

**Aquatic Field Dissipation (835.6200, Waived)**

Data on aquatic field dissipation can be waived because silver is an inorganic ion or complex that will not degrade.

**Monitoring of Representative U.S. Waters (no guideline, Waived)**

This data requirement can be waived because silver is a naturally occurring metal that is often found as a complex with negatively-charged ions. There is a National Secondary Drinking Water Regulation of 0.1 mg/L or less for silver.

The DER for MRID 47707809 is attached to this memorandum. If there are any questions, please contact Jim Breithaupt at 703-305-5925 or at [breithaupt.james@epa.gov](mailto:breithaupt.james@epa.gov).

Sign-off Date : 12/02/09  
DP Barcode No. : D364888



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

October 28, 2009

DP BARCODE: D364188

MRID : 477078-00, 477078-01, 477078-02

SUBJECT: Silver Assembly with Washing Machine

REG. NO. OR FILE SYMBOL: 82544-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Silver (072501)

CAS Number: (7440-22-4)

TEST LAB: N/A

SUBMITTER: Samsung Electronics Co., LTD.

GUIDELINE: 830 Groups "A & B"

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 11/02/09

COMMENT:




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

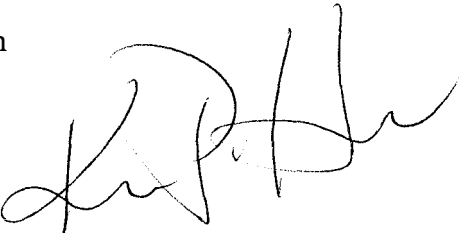
OFFICE OF  
PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

October 28, 2009

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 82544-R.

**From:** Juan F. Negrón, Chemist   
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) 

**To:** Marshall Swindell / Karen Leavy  
PM Team 33

**Applicant:** Samsung Electronics Co., LTD.

**Action code:** A500

**Due date:** 01/09/10

**Product Formulation**

**Active Ingredient(s):**

Silver

% by wt.  
0.006



## BACKGROUND:

On behalf of the registrant, Samsung Electronics Co., LTD., the consultant, Keller and Heckman LLP, has submitted an application for registration of an integrated new end-use product system, **Silver Assembly with Washing Machine**. A preliminary chemistry review of this submission was made by CSC Systems & Solutions LLC (CSC). All relevant comments from the April 22, 2009 CSC review were incorporated into this final product chemistry review. This product is a front-loading washing machine equipped with a factory-installed with “Silver Assembly” that is designed to control odor-causing bacteria on washed fabrics and in the washer drum and washer water system. The Product Chemistry Reviewer has received the following documents:

- Confidential Statement of Formula (CSF), dated 03/05/09, for the basic formulation.
- Letters, dated 04/09/08, 02/10/09, and 03/19/09.
- A label, dated 03/19/09 pin punched.
- Self-Certification statement for the physical/chemical properties (PR Notice 98-1), dated 03/05/09.
- A study titled “Product Identity and Composition) Volume 2, MRID 477078-01.
- A study titled “Preliminary Analysis” Volume 3, MRID 477078-02.
- A study titled “Corrosion Characteristics – Waiver Request” Volume 4 MRID 477078-03.

## FINDINGS:

1. The CSF, dated 03/05/09, for the basic formulation is revised.
2. The CSF and the label have the same nominal.
3. The CSF shows wider certified limits for all components. See study titled “Product Identity and Composition) Volume 2, MRID 477078-01 for justification of wider certified limits for all components.
4. The total weight is blank in box 17 of the CSF for the basic formulation.
5. Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS (830.1700 Preliminary Analysis), and OPPTS 830.1800 (Analytical Method). See the “Recommendations” section of this report for deficiencies. See also Table A of this report.
6. The preliminary analysis, MRID # 477078-02, indicates that the study was conducted in the manufacturing research and quality control laboratory of the silver bar supplier (which means the assay was conducted in Korea). The laboratory has not established the full record keeping requirements nor full written standard operation procedures (SOPs) required by 40 CFR Part 160. The study reveals that these assays are the certificates of analyses of the raw material for the AI.

7. A waiver for conducting corrosion characteristics testing in response to OPPTS 830.6320 is based on the silver in the Silver Assembly that should last 10 years or about 1200 silver cycles. The study reveals that sterling silver contains a minimum of 92.5% colloidal silver and for centuries it had been regularly used in household cutlery and worn on the body as jewelry. These routine uses of silver demonstrated that at high purities, the material is non-corrosive.  
When the silver ion generator is activated, the pure silver atoms have an electron stripped away by electrolysis. The registrant has conducted a study where the silver plates' ability to deliver the required silver concentrations over the proposed life of the silver plates (see page (4, thru6) of 6 MRID # 477078-03 for data and test results) is demonstrated.
8. The registrant has indicated that the OPPTS 830.1800 Enforcement Analytical Method is the ICP Method. However, no copy of the method has been provided.
9. The 830 Group B guidelines were not reported.
10. Certain information on the product label could be improved, as noted in the "Recommendations" section of this report.

#### **CONCLUSION:**

The CSF, dated 03/05/09, for the basic formulation is acceptable with comment. The justifications for wider certified limits for all components are acceptable. The registrant must provide 830 Group "B" guidelines results. See table below for updating guidelines.

#### **RECOMMENDATIONS:**

1. The registrant must indicate the total weight of [REDACTED] in the CSF for the basic formulation.
2. The preliminary analysis must be based on the product, **Silver Assembly with Washing Machine**. Testing must be conducted in compliance with GLP. OPPTS 830.1000(e) (2) (v) states that all provisions of the GLP standards apply to preliminary analysis studies.
3. To satisfy OPPTS 830.1800 (Analytical Method) requirements, a copy of an analytical method suitable for enforcement purposes must be provided for the active ingredient (i.e., silver). This method must be formatted and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, Limit of detection (LOD), limit of Quantification (LOQ), and Calculations. A reference to "ICP Method" is not sufficient.
4. The registrant must submit the OPPTS 830 Group "B" guidelines.

5. The following revision to the product label is recommended:
- Under the “Disposal” section of the product label, identify disposal options for the container using the following (or similar text): “Place in trash or offer for recycling, if available.”

**PRODUCT CHEMISTRY REVIEW****I. CONFIDENTIAL STATEMENT OF FORMULA****a. Type of formulation and source registration:**

- Non-integrated formulation system [ ]
- Are all TGAs used registered? Yes [x]      No [ ]
- Integrated formulation system [X]
- If “ME-TOO,” specify EPA Reg. No. of existing product: \_\_\_\_\_

**b. Clearance of inerts for non-food or food use:**

The product is cleared for non-food use under 40 CFR §§ 180.940 and 180.950.  
Yes [x]      No [ ]

**c. Physical state of product:***Solid***d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.**Yes [X]      No [ ]

*Note: The density of the silver component was reported to be 10.49 g/mL. A density value for the silver, [REDACTED] was not provided.*

**e. The NCs and CLs are acceptable.**Yes [X]      No [ ]

*Note: Non-standard certified limits were proposed for the active ingredient, [REDACTED]. An explanation of the basis for the non-standard limits was provided. The explanations are acceptable.*

**f. Active ingredient(s)**

	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
Silver	0.006	0.004	0.008

**g. For products produced by an integrated formulation system:**

- Do all impurities of toxicological significance have a UCL?  
Yes [ ]      No [ ]      Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ]      No [ ]      Not applicable [X]

## II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- |  |         |        |
|--|---------|--------|
| • 10% or more of a petroleum distillate: | Yes [ ] | No [X] |
| • 1.0% or more of methyl alcohol:        | Yes [ ] | No [X] |
| • sodium nitrite at any level:           | Yes [ ] | No [X] |
| • a toxic List 1 inert at any level:     | Yes [ ] | No [X] |
| • arsenic in any form:                   | Yes [ ] | No [X] |

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [X]

**Table A:**  
**Product Chemistry (830 Series, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	477078-01
830.1600 Description of Materials	A	477078-01
830.1620 Production Process <sup>2</sup>	A	477078-01
830.1650 Formulation Process <sup>3</sup>	A	477078-01
830.1670 Formation of Impurities <sup>4</sup>	A	477078-01
830.1700 Preliminary Analysis <sup>5</sup>	N – Results from the analysis of five batches of the product were not provided. The registrant provided five certificate of analysis from the supplier, Korea. Testing was <u>not</u> conducted in compliance with GLP.	477078-02
830.1750 Certified Limits <sup>6</sup>	A	477078-01
830.1800 Analytical Method <sup>7</sup>	N – Reference was made to an ICP Method. A copy of an analytical method suitable for enforcement purposes must be provided. This method must be formatted and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, and Calculations.	477078-01
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NR	[Not required for end-use products.]	
830.6303 Physical State	A	Solid	
830.6304 Odor	NR	[Not required for end-use products.]	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	[Not required for end-use products.]	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	See 82544-E, DP #364189	
830.6315 Flammability/Flame Extension	A	See 82544-E, DP #364189	
830.6316 Explodability	A	See 82544-E, DP #364189	
830.6317 Storage Stability	G		
830.6319 Miscibility <sup>1</sup>	A	See 82544-E, DP #364189	
830.6320 Corrosion Characteristics	A	The active ingredient of the product is silver, which is non-corrosive at high concentrations.	477078-03
830.6321 Dielectric Breakdown Voltage	A	See 82544-E, DP #364189	
830.7000 pH <sup>2</sup>	A	See 82544-E, DP #364189	
830.7050 UV/Visible Absorption	NR	[Not required for end-use products.]	
830.7100 Viscosity	A	See 82544-E, DP #364189	
830.7200 Melting Point/Melting Range	NR	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NR	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	See 82544-E, DP #364189	
830.7370 Dissociation Constants in Water	NR	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NR	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NR	[Not required for end-use products.]	
830.7950 Vapor Pressure	NR	[Not required for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate. \* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid ; <sup>2</sup>If product is dispersible with water





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES,  
AND TOXIC SUBSTANCES

November 23, 2009

**MEMORANDUM:**

**Subject:** Occupational and Residential Exposure and Risk Assessments for the New Use of Silver Ions in Washing Machines

**To:** Marshall Swindell, Product Manager  
Regulatory Management Branch I  
Antimicrobials Division

**From:** Cassi L. Walls, Ph.D., Chemist *Cassi L. Walls*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division

**Thru:** Norm Cook, Branch Chief *Norm Cook*  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division

**DP Barcode:** 364192

**Chemical No.:** 072506

**Chemical Name:** Silver

## 1.0. Action Requested

The Antimicrobial Division's (AD) Regulatory Management Branch I has requested that Risk Assessment and Science Support Branch (RASSB) conduct exposure and risk assessments to support Samsung Electronic Co., LTD's application for a proposed use of a washing machine that releases silver ions into the wash tub during the final rinse. The silver ion active ingredient binds to the fabric and reduces odor-causing bacteria growth.

## 2.0. Summary of Findings

Based on the use patterns for the proposed new use of silver assembly with washing machine and the toxicity information for silver ions, RASSB concludes that there is no concern for occupational or residential dermal exposures. The short- and intermediate-term residential incidental oral Margins of Exposures (MOEs) are above the Target MOE of 300 and are therefore not of a concern. However, MOEs for the long-term incidental oral scenario exceed the Agency's level of concern (i.e., MOEs are less than the Target MOE of 3). This is a conservative screening-level assessment and could it be refined by additional data. Specifically, since no chemical specific leaching data were available, it was assumed that 50% of the silver ions bound to the fabric were extracted during the mouthing/sucking of the fabric. Thus, a silver-specific saliva extraction study could refine the 50% assumption and overall assessment.

## 3.0. Background

AD's Regulatory Management Branch I, received an application from Keller and Heckman LLP on behalf of Samsung Electronics Co., LTD for a new use application for registration of the Silver Assembly with Washing Machine containing 5.4 gram solid silver electrodes as the active ingredient. This use site is considered to be a non-food indoor use, therefore occupational and residential non-dietary exposures were considered in this assessment.

## 4.0. Product Use Profile

The Samsung Washing Machine is a silver ion generator that contains solid silver plates which act as electrodes in the water inlet system. During the final rinse cycle, the pure silver atoms have an electron stripped away by electrolysis where 4.5 mg of ionic silver is released into the wash tub. The use of the silver cycle is intended to reduce odor-causing bacteria growth on fabrics. Silver ions are antimicrobial at concentrations greater than 0.20 ppm.

## 5.0. Selection of Toxicological Endpoints for the Non-dietary Assessment

A complete discussion of the endpoints selected for use in the risk assessments can be found in the toxicology memo D356736, "**Silver** : *Interim Position for Toxicological End-points Used for Assessment for the Proposed Amendments to JMAC Composite PG (EPA Reg. #49403-34) and Proposed New Label, Nipacide® JLP10 (EPA*

Reg. # 49403-GI)” dated May 13, 2009 . A summary of the toxicity endpoints used in this assessment is provided below.

### 1. Short term and intermediate term oral exposure routes:

The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.

Acceptable MOE = 300 (10x - Intra UF, 10X - inter UF, and 3 x for database UF);

$$\text{Short and Intermediate Oral Interim Endpo int} = \frac{64.6 \text{ mg / kg / day}}{300} = 0.22 \text{ mg / kg / day}$$

Note: The applied database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies.

### 2. Short term and intermediate term inhalation exposure routes:

The NOAEL of 64.6 mg/kg/day for silver ion is based on no significant adverse effects identified at the highest level tested (NTP, 2002). The only maternal toxicity observed at 100 mg/kg of silver acetate (64.6 mg/kg/day of silver ion) is less than 8% body weight loss when compared to controls and the clinical sign noticed is piloerection.

Acceptable MOE = 1000 (10x - Intra UF, 10X - inter UF, 3 x for database UF, and 3x for route to route extrapolation);

$$\text{Short and Intermediate Inhalation Interum Endpo int} = \frac{64.6 \text{ mg / kg / day}}{1000} = 0.06 \text{ mg / kg / day}$$

Note: The database safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive and neurotoxicity studies. The safety factor of 3x is applied for extrapolating to an inhalation end-point from an oral study.

### 3. All dermal exposure routes:

No dermal risk assessment is required because silver ions bind to the tissue at the site of dermal contact and no systemic effects are likely to occur. However, warning language such as “Dermal exposure may cause skin color change” should be included in the labeling.

#### 4. Long -term oral exposure route:

The long-term oral NOAEL is based the drinking water Secondary Maximum Contaminant Level (SMCL) level of 0.1 mg/L (0.003 mg/kg/day) where the effects are based on skin discoloration and graying of the whites of eyes (Argyria). An additional safety factor of 3 is applied to address the residual uncertainty associated with the missing reproductive, developmental, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver. Acceptable MOE = 3

$$\text{Long Term Oral Interum Endpoint} = \frac{0.003 \text{ mg / kg / day}}{3} = 0.001 \text{ mg / kg / day}$$

#### 5. Long-term Inhalation exposure route:

The long-term inhalation NOAEL is based on OSHA's 8-hour TWA of 0.01 mg/m<sup>3</sup> (0.001 mg/kg/day) where the effects are based on argyria. An additional safety factor of 3x is applied to address the residual uncertainty associated with the missing reproductive, inhalation study, neurotoxicity and chronic toxicology studies. A safety factor of 3 instead of 10 is used based on historical data for silver.

$$\text{Long Term Inhalation Interum Endpoint} = \frac{0.001 \text{ mg / kg / day}}{3} = 0.0003 \text{ mg / kg / day}$$

Note: These proposed end-points apply to silver ion only. For other silver complexes (e.g., silver zeolites, nano-silver), AD will evaluate the endpoints on a case by case basis.

#### 6.0. Human Exposure Assessment

Based on the use pattern of the Silver Assembly Washing Machine, RASSB has determined that there is a potential for dermal exposures to professional handlers replacing the silver plates and post-application dermal exposures to adults and children wearing clothing laundered in the machine. However, based on hazard assessment of silver ions, RASSB also concluded no risk assessment is required since systemic effects via the dermal route are not likely to occur. There is also a potential for post-application incidental oral exposure to children mouthing clothing laundered in the Silver Assembly Washing machine. Thus, only the incidental oral exposure scenario is quantitatively assessed in this document.

assessment, AD identified the following uncertainty/limitation of the study. The study showed that the silver concentration continuously increases with each additional wash; however, it is uncertain on whether 100 washes is enough to represent an upper-limit of silver concentrations on items such as nursery blankets or plush toys. Assuming a nursery item such as a blanket can undergo 2 washes per week over the course of its lifetime (approximately 2 years), the number of total washes could be approximately 200 rather than 100. AD acknowledges that a certain amount of silver could be dislodged between washings however this value is unknown and can not be incorporated into the assessment at this time.

- D: The fabric density of 10 mg/cm<sup>2</sup> is based on the density of mixed cotton and synthetic fabrics (HERA, 2005).
- Fm: The surface area of fabric/textile mouthed by children is 100 cm<sup>2</sup>/day (standard AD assumption).
- SE: The saliva extraction efficiency is 50% (USEPA, 2001). A chemical specific saliva extraction study could be used to refine this assumption.
- BW: The average toddler (3 years old) bodyweight is 15 kg (rounded from 15.1 kg) based on the average of the 50 percentile male and female body weights listed for 42.5 month old children in the CDC growth charts (US EPA, 1997).

## **Results**

The calculation of the short-, intermediate-, and long-term incidental oral exposures and MOEs are presented in Table 1. All of the ST/IT oral MOEs are above the Target MOE of 300 and are therefore not of a concern. However, the LT MOEs are below the Target MOE of 3 and are of concern. A saliva extraction study could further refine this assessment.

**Table 1. Oral Exposures and MOEs Resulting from the Use of the Silver Assembly Washing Machine**

	Polyester Midpoint (50 washes)	Polyester Maximum (100 washes)
Silver conc on fabric (%)	0.01%	0.018%
Fabric density (mg/cm <sup>2</sup> )	10	10
Surface area mouthed (cm <sup>2</sup> )	100	100
Saliva Extraction (%)	50%	50%
Body weight (kg)	15	15
Oral Exposure (mg/kg/day)	0.003	0.006
ST/IT Oral NOAEL	64.6	64.6
ST/IT Oral MOE (Target MOE = 300)	19,000	11,000
LT Oral NOAEL	0.003	0.003
LT Oral MOE (Target MOE = 3)	0.9	0.5

## 6.1 Residential Post-application Exposures

RASSB conducted a conservative screening level assessment to evaluate children's post-application incidental ingestion exposure to silver ions remaining on laundered fabric in Samsung's Silver Assembly Washing Machine. Incidental ingestion exposure occurs via mouthing treated clothing or nursery items (i.e., blankets, plush toys, etc). Typically, most products used in a residential setting result in exposures occurring over a short-term time duration (1 to 30 days). However, if the products are used on a routine basis (i.e., once a week) and the active ingredient has a long indoor half-life, exposures may occur over an intermediate-term time duration (30 days – 6 months). AD believes that exposure to silver ions will occur on a routine basis for children mouthing laundered clothing or nursery items over the lifetime of the item (i.e., > 6 months). Therefore, short- and intermediate- and long-term exposures were necessary to assess for the post-application washing machine scenario.

This exposure can be calculated using the following equation that is *based* on guidance provided in Human and Environmental Risk Assessment (HERA) Guidance Document (2005):

$$\text{PDD} = F \times D \times F_m \times \text{SE} / \text{BW}$$

where

PDD	=	Potential daily dose (mg/kg/day)
F	=	fabric residue concentration (%)
D	=	fabric density (mg/cm <sup>2</sup> )
F <sub>m</sub>	=	fabric area mouthed (cm <sup>2</sup> /day)
SE	=	saliva extraction efficiency (%)
BW	=	body weight (kg)

Assumptions:

- F: The fabric residue concentration (0.01% and 0.018%) is based on data provided in Samsung's fabric analysis (*Determination of Fabric Concentrations from Washing Machines when the Silver Ion Generator Feature is Selected*; March 2009). This study evaluated two test series. One series ran 90 wash cycles with polyester fabrics and the other series ran 100 wash cycles using cotton fabrics. The results of both series show that the silver concentration on the fabric consistently increases with each additional washing where the silver bonds more to polyester than cotton. The silver concentration on polyester was 40 ppm (or 0.004%) after 30 washes and 180 ppm (or 0.018%) after 90 washes while the concentration on cotton was 4 ppm (0.0004%) after 2 washes and 96 ppm (or 0.0096%) after 100 washes. For purposes of this assessment, AD used the silver concentration on polyester of 100 ppm (or 0.01%) which represents the cumulative total concentration after 50 washes and the maximum silver concentration on polyester of 180 ppm (or 0.018%) which represents the cumulative total concentration after 90 washes.
  - Although the data from Samsung's fabric analysis was used in this

It should be noted that the registrant submitted its own exposure assessment. This assessment was evaluated but RASSB noted the following limitations:

- The assessment assumes that only 50% of each thread is able to contact the body. This assumption appears to be reasonable for the dermal assessment however both sides of the fabric are mouthed during the incidental oral exposure scenario.
- It appears that a calculation error was made in the silver exposure per fabric square parameter. The registrant reports this value as  $1 \times 10^{-5}$  mg/cm<sup>2</sup> however the actual value is  $1 \times 10^{-3}$  mg/cm<sup>2</sup>. Making this correction would result in an MOE 100 times lower than the one reported by the registrant.

## **7.0 Conclusions**

Based on the use patterns for the proposed new use of Samsung's Silver Assembly Washing Machine, RASSB concludes that there are no dermal concerns for occupational and residential users. Additionally, none of the ST/IT MOEs for the residential child post-application incidental oral scenarios exceed the Agency's level of concern (i.e., all MOEs are greater than the Target MOE of 300). However, the LT incidental oral MOEs are below the Target MOE of 3 and are of concern. A silver ion-specific saliva extraction study could be used to refine this assessment.

## **8.0. References**

- HERA, 2005. Human and Environmental Risk Assessment, Guidance Document Methodology, February, 2005 (<http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf>).
- USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.
- USEPA. 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.



Office of Prevention, Pesticides,  
and Toxic Substances

Date: November 03, 2009

SUBJECT: Ecological Assessment of Samsung Electronics Co. Silver Assembly Washing  
Machine Registration Request and Ecotoxicity Test Data Waivers

DP Barcode: DP364892

PC Code: Silver Ion Generating Bar

FROM: Richard C. Petrie, Agronomist, Team 3 Leader  
OPP/AD/RASSB  
Antimicrobial Division (7510P)

*Richard C. Petrie* 11/03/09

THRU : Norm Cook.  
Chief, RASSB  
Antimicrobial Division (7510P)

*Norm Cook* 11/3/09

TO: Marshall Swindell, RM 33  
OPP/AD/RMB1  
Antimicrobial Division (7510P)

Samsung Electronics Co. is requesting registration of a silver ion generating washing machine. No ecotoxicity studies were submitted. The registrant has referenced an avian acute oral toxicity test: MRID 464533-01. This study used 99.6% silver chloride. The LD50 value was >2250 mg ai/Kg and the NOAEL was 1350 mg ai/Kg. This study is an acceptable (Core) study and fulfills the guideline requirement 850.2100 (acute avian oral toxicity) required for label environmental hazard statement purposes. **Waiver requests for 850.2200 (avian dietary toxicity) and 850.2300 (avian reproduction) are not granted but held in reserve pending further assessment of risk to nontarget and endangered/threatened avian and mammalian species.**

The registrant has referenced the EPA/OPP Reregistration Eligibility Document for Silver, Case 4082, 1992, aquatic toxicity data and ecological effects risk assessment. The registrant has also cited literature. The RASSB is currently utilizing the following silver ion acute and chronic endpoints for aquatic organisms:

The Silver RED was published in 1992. Since publication of the Silver RED three synoptic reviews of silver ecotoxicity data and risks to the environment have been published as follows:



- 1.) Eisler, R. 1996. "Silver Hazards To Fish, Wildlife, and Invertebrates: A Synoptic Review". Bio. Rpt. 32, Contaminant Hazard Reviews, September 1996. Patuxent Wildlife Research Center, U.S. National Biological Service, U.S. Dept. of Interior, Laurel, MD 20708. pp.63.
- 2.) Howe, P.D. and S. Dobson. 2002. "Silver and Silver Compounds: Environmental Aspects". Concise International Chemical Assessment Document 44. Centre for Ecology and Hydrology, Monks Wood, United Kingdom. World Health Organization. pp.34.
- 3.) USEPA, WQC. 2007. "2007 Draft Update Of Ambient Water Quality Criteria For Silver". October 19, 2007. Contributors: Gorsuch, J. M. Rooni, W.K. Bing, P. Paquin, R. Santore, K. Brix. Pg. 27-37.

Available ecotoxicity data for silver indicates that silver chloride is **very highly toxic to aquatic animals and plants** (all types of freshwater and marine including fish, invertebrates, mollusks, frogs, insects, protozoa, algae). Numerous studies provide a wide range of ecotoxicity EC, LC, and NOAEC values depending on the silver formulation used in the study and other experimental variables. Silver ion is considered by researchers to be the most biologically available form of silver. Silver nitrate is considered to be more toxic to aquatic organisms than silver thiosulfate, silver chloride, or silver sulfide (Eisler, 2007 – pg. 9). Researchers acknowledge that little is known of the biocidal properties of  $Ag^{2+}$  and  $Ag^{3+}$  that are active ingredients in disinfectants and used increasingly in water purification systems (Eisler, 2007 – pg. 50).

**The most sensitive endpoints summarized from literature for silver ion are:**

**ACUTE AQUATIC ORGANISM ENDPOINTS**

<b>Aquatic Organism toxicity</b>	<b>EC/LC50 - ug/L (ppb)</b>
Freshwater Invertebrate – ( <i>Daphnia magna</i> )	0.19 (EPA, MRID0005496)
Marine Invertebrate – American oyster ( <i>Crassostrea virginica</i> )	5.80 (Eisler, 1996)
Freshwater Fish – Fathead minnow ( <i>Pimephales promelas</i> )	1.20 (WQC, 2007)
Marine Fish – Summer Flounder ( <i>Paralichthys dentatus</i> )	4.70 (WHO, 2002)
Freshwater Plant – algae ( <i>Scenedesmus sp.</i> )	50.00 (Estimate) (WHO, 2002)
Marine Plant – algae ( <i>Prorocentrum mariaelebouriae</i> )	3.30 (WHO, 2002)
Terrestrial Plant – lettuce ( <i>Lactuca sativa</i> )	>750.00 seedling emergence

	(WHO, 2002)
Amphipod – ( <i>Hyaella azteca</i> )	1.90 (WHO, 2002)
Leopard Frog – ( <i>Rana pipiens</i> )	10.00 (WHO, 2002)
Insect – Stonefly ( <i>Pteronarcys californica</i> )	2.50 (Eisler, 1996)
Protozoa – ( <i>Spirostomum ambiguum</i> )	8.80 (Eisler, 1996)

### **CHRONIC AQUATIC ORGANISM ENDPOINTS**

<b>Aquatic Organism</b>	<b>NOAEC - ug/L (ppb) toxicity</b>
Freshwater Invertebrate – ( <i>Daphnia magna</i> )	3.22 (21 day, survival) (WQC, 2007)
Marine Invertebrate – Mussel ( <i>Mytilus edulis</i> )	1.00 (21 day LOAEL, growth) (WHO, 2002)
Freshwater Fish – Rainbow trout ( <i>Oncorhynchus mykiss</i> )	0.17 (18 month LOAEL survival) (WHO, 2002)
Marine Fish – Winter Flounder ( <i>Pleuronectes americanus</i> )	10.00 (60 day depressed liver activity) (Eisler, 1996)
Amphipod – ( <i>Hyaella azteca</i> )	0.95 (21 day survival) (WHO, 2002)
Insect – Mayfly ( <i>Isonychia bicolor</i> )	0.30 (14 day molting inhibition (WHO, 2002)

### **BIO-CONCENTRATION FACTORS (BCF's)**

<b>Source</b>	<b>Aquatic Organism</b>	<b>BCF</b>
Eisler, 1996	Freshwater Plants	200X
Eisler, 1996	Marine Algae	13,000 – 66,000X
Eisler, 1996	Protozoa	7,000 – 40,000X
Eisler, 1996	Fish – Common Carp ( <i>Cyprinus carpio</i> ) (41 day exposure, 42 day depuration)	73X (at 41 days) 866X (at 41 days in liver) 560X (at 41 days in digestive tract) 299X (at 41 days in kidneys) 155X (at 41 days in spleen) 109X (at 41 days in bladder) (1/3 of silver remained after depuration for 42 days)
Eisler, 1996	Fish – Brown trout ( <i>Salmo trutta</i> ) (57 days exposure, 28 days depuration)	2.7X (70% in liver, no change during depuration, 282X liver BCF)
WHO, 2002 (pg. 11)	California blackworm ( <i>Lumbriculus variegatus</i> ) (28 day exposure)	0.18X
WHO, 2002 (pg. 10)	Grass shrimp ( <i>Palaemonetes pugio</i> )	70 – 4,000X
WHO, 2002 (pg. 9)	Diatom Brown algae	210X 240X

	Mussels Scallops Oysters	330X 2,300X 18,700X
Eisler, 1996	Caribou ( <i>Rangifer tarandus</i> )	3.0X bone 1.3X kidney 80X liver 0.3X muscle

### **Environmental Levels of Silver**

- Silver concentrations in biota were greater in organisms near sewage outfalls, electroplating plants, mine wastes, and silver iodide-seeded areas (WHO, 2002).
- Approximately 30-70% of silver in surface waters in the US is attached to suspended particles depending on water hardness and salinity (WHO, 2002).
- Background silver level in rivers, lakes, and estuaries from pristine, unpolluted areas is approximately 0.01 ug/liter (WHO, 2002).
- Background silver levels in urban and industrial areas range from 0.01 to 0.1 ug/liter (WHO, 2002).
- Silver can remain attached to ocean sediments for approximately 100 years under conditions of high pH, high salinity, and high sediment concentrations of iron, manganese oxide and organics (WHO, 2002).
- Maximum concentrations of total silver recorded in field collections of living organisms were 1.5 mg/Kg silver dry weight in liver of marine mammals; 2.0 in liver and 6.0 in bone of trout; 7.0 in kidneys and 44.0 in liver of birds; 14.0 in marine algae and macrophytes; 30.0 in annelid worms; 110.0 in whole mushrooms; 133.0 to 185.0 in soft parts of clams and mussels; and 320.0 in whole gastropods BCF's are variable among species of mussels (WHO, 2002).
- Benthic bivalve mulluscs can take up silver from sediment. The accumulation of silver by benthic organisms from marine sediment is attributed, in part, to the formation of stable complexes of silver with chlorine, which, in turn, favors the distribution and accumulation of silver. The ½ life persistence of silver is 149 days in the American oyster and 26 days in the Pacific oyster (WHO, 2002).
- Marine annelids and clams accumulate dissolved and sediment-bound forms of silver. Uptake of silver from sediments by marine polychaete annelids decreased in sediments high in humic substances or copper but increased in sediments with elevated concentrations of manganese or iron (WHO, 2002).
- Terrestrial plant concentrations of silver are usually less than 0.1 mg/Kg dry weight (WHO, 2002).
- Certain algae readily accumulate silver and once incorporated is tightly bound to the cell membrane. Silver accumulation in marine algae up to 14.1 mg/Kg dry weight was due mainly to adsorption rather than uptake. Silver bioconcentration factors of 13,000 to 66,000X are common for algae. Algae dosed for 4 days with 0.5 and 0.05 ug/L silver and fed to marine and freshwater copepods had significant adverse effects on copepod reproduction (WHO, 2002).

- Silver concentrations in caddisflies and chironomid larvae usually reflect silver concentrations in sediments. Another study showed a high correlation of silver bioaccumulation in arthropods with lake water silver concentrations 20 days earlier (WHO, 2002).
- Relatively high concentrations of silver were found in the livers and body hair of seals and sea lions with 70% of body burden in the liver. Silver concentrations in mg/Kg body weight were 0.04 to 0.55 in Northern fur seal, 0.1 to 1.04 for Steller sea lions, and 0.03 to 0.83 for Harbour seals. Silver in Alaskan beluga whale liver was 2 orders of magnitude higher than for any other marine mammals (no adverse effects were reported (WHO, 2002).
- The environmental fate and transformation of silver in the environment is subject to many variables not well understood. There is a lack of field collected flora and fauna samples for silver (Eisler, 1996).

Aquatic organisms that rely on arthropods and/or aquatic plants for the bulk of their diet may have greater potential for exposure to silver. Benthic annelids and mollusks are also expected to be exposed to higher silver concentrations from sediments.

**Registrant requests for aquatic organism test waivers are accepted for the following:**

**850.1025 (oyster acute), 850.1035 (Mysid acute), 850.1045 (Penaeid acute), 850.1055 (Bivalve acute), 850.1075 (fish acute), 850.1400 (Fish early life stage), 850.1300 (Daphnia chronic), 850.1350 (Mysid chronic), 850.1500 (Fish life-cycle), 850.1710 (Oyster BCF), and 850.1730 (Fish BCF) as long as the registrant is willing to accept the endpoints cited above from literature.**

**The following waiver requests are held in reserve: 850.1850 (Aquatic food chain transfer), 850.1950 (Field testing for aquatic organisms).**

**The following waiver requests for sediment organism toxicity tests are held in reserve: 850.1735 (Whole sediment acute marine invertebrate), 850.1736 (Whole sediment acute fresh-water invertebrate), and Whole Sediment chronic fresh-water and marine invertebrates (no guideline number).**

**The following waiver requests for insect pollinator testing are accepted: 850.3020 (Honeybee acute) and 850.3030 (Residue toxicity to honeybees).**

**Above studies mentioned as reserved are reserved pending final risk assessments for sediments, land application of sewage sludge, and endangered/threatened species.**

## **Ecological Risk Assessment and Characterization**

Risk assessment and characterization integrates exposure and toxicity information to evaluate the potential for adverse ecological effects. Risk quotients (RQs) are determined for each taxa or

ecological group by comparing exposure estimates (Estimated Environmental Concentrations, EECs) to the available acute and chronic ecotoxicity values, where:

$$RQ = \text{Exposure estimate (EEC)} / \text{Toxicity value}$$

RQs are compared to OPP's levels of concern (LOCs). Exceedance of an LOC indicates a potential for acute or chronic adverse effects on nontarget organisms and identifies a need for regulatory action to mitigate risk. LOCs currently address the following risk presumptions:

acute:	regulatory action may be warranted to reduce or preclude acute exposure
acute, listed species:	additional regulatory action may be warranted to protect listed (i.e., endangered or threatened) species
chronic:	regulatory action may be needed to reduce or preclude chronic exposure

The LOCs for the various risk presumptions are listed below for terrestrial and aquatic animals and plants:

	<u>Aquatic Animals</u>	<u>Terrestrial Animals</u>	<u>Plants</u>
Acute:	0.5	0.5	1
Acute, listed species:	0.05	0.1	1
Chronic:	1	1	n/a

The following toxicity endpoints are used as inputs to the RQ method for expressing risk:

<u>Aquatic Animals</u>	
Acute:	Lowest tested EC50 or LC50 for freshwater fish and invertebrates and estuarine/marine fish and invertebrates
Chronic:	Lowest NOEC for freshwater fish and invertebrates and estuarine/marine fish and invertebrates (early life-stage or full life-cycle tests)
<u>Terrestrial Animals</u>	
Avian acute:	Lowest LD50 (single oral dose) and LC50 (subacute dietary)
Avian chronic:	Lowest NOEC (21-week avian reproduction test)
Mammalian acute:	Lowest LD50 from single oral dose test.

Mammalian chronic:	Lowest NOEC for two-generation reproduction test
<u>Plants</u>	
Terrestrial:	Lowest EC25 values from both seedling emergence and vegetative vigor for both monocots and dicots
Terrestrial listed:	Lowest EC05 or NOEC for both seedling emergence and vegetative vigor for both monocots and dicots
Aquatic vascular and algae:	Lowest EC50
Aquatic vascular listed:	NOEC or EC05

When available, toxicity measures or other appropriate information from non-guideline studies or from the open literature also may be used to characterize and refine risks.

EPA generally uses computer simulation models to estimate exposure of aquatic organisms to an active ingredient (e.g., PDM-4). These models estimate EECs in surface waters and sediment using product-label information (e.g., treatment site, application rate, application method) and available environmental-fate data to determine how rapidly the pesticide degrades and its expected movement in environmental compartments.

For aquatic organisms, the following EECs are typically used to calculate the RQ for each taxa:

<u>Fish</u>
Acute: Instantaneous Chronic: 60-day average
<u>Invertebrates</u>
Acute: Instantaneous Chronic: 21-day average
<u>Plants</u>
Acute: Instantaneous Chronic: Not applicable

**Based on available data for silver ion, silver is very highly toxic to aquatic animals and plants on an acute basis (0.19 to 50.0 ug ai/L). Also based on available literature, aquatic plants and animals may be adversely affected on a chronic basis upon exposure to levels of silver as low as 0.17 to 3.22 ug ai/L in the environment. Silver ion is not expected to be**

toxic to avian or mammalian species on an acute basis, however, a complete assessment was not conducted.

#### **Down-the-Drain and Bio-ligand Modeling Results:**

The Aquatic Exposure Estimate for silver in surface water from the Down The Drain Model is 0.00652 ug/L for 10 percentile 1Q10. This silver concentration was used as input in the Biotic Ligand Model (BLM) to estimate the concentration of silver in surface water.

The BLM model version 2.2.3 was used for this simulation. The BLM simulation was run for toxicity and speciation modes and the selected organism was *Daphnia magna*. The free Ag concentrations from the toxicity and speciation runs were used to calculate Risk Quotients (RQs) for 811 sites throughout the United States.

The results from the BLM model run are shown in Appendix A. The RQs were calculated and compared to 0.5 and 0.05. According to these results, all calculated RQs for *daphnia magna* were less than 0.05 indicating no exceedences.

#### **Endangered Species Considerations:**

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify

if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment. The proposed silver ion generating washing machine will produce effluent that will be diverted to surface waters and therefore is not considered to be a minimal environmental risk use. Down-the-drain and bio-ligand (BLM) aquatic modeling results predict that endangered/threatened species levels of concern (LOC's) are not exceeded using the most sensitive species (*Daphnia magna* – acute toxicity endpoint EC50 value of 0.19 ug/L), and using the most current market projections provided by the registrant.

If it is determined that there is potential for the proposed material preservative uses to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects, the refined assessment should involve clear delineation of the action area associated with these uses and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment. An endangered species effect determination will not be made at this time.

### **Required Environmental Hazards Label Statement:**

**Silver labels must have the following Environmental Hazards label statements:**

- “This pesticide is toxic to fish, aquatic invertebrates, oysters, clams, and shrimp.”
- “Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.”



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Monday, May 11, 2009

MEMORANDUM

SUBJECT: Acute Toxicity Review for

<u>EPA File Symbol:</u>	<u>Product Name:</u>	<u>DP Barcode:</u>
82544-R	Silver Assembly w/Washing Machine	364185
82544-E	Silver Assembly	364186

FROM: Earl Goad, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Earl Goad*  
5/11/2009

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Karen Hicks*

THRU: Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Samsung Electronics Co., LTD  
416 Maetan-3dong, Yeongtong-gu  
Su-won-City, Gyeonggi-do, KOREA 443-742

PRODUCT FORMULATION FROM LABEL:

<u>Active</u> <u>Ingredient(s):</u>	<u>Silver Assembly w/</u> <u>Washing Machine</u>	<u>Silver</u> <u>Assembly Only</u>
Silver (metallic)	0.006%	25.9%
Other Ingredient(s): <span style="background-color: black; color: black;">XXXXXXXXXX</span>	99.994%	74.1%
Total:	100.000%	100.0%

\*Inert ingredient information may be entitled to confidential treatment\*

I) BACKGROUND:

The registrant has submitted a document requesting that EPA waive the acute toxicity data requirements for their product(s) containing 99.9% silver electrodes as the active ingredient as a component assembly (EPA Symbol #: 82544-E) or as in the assembly included installed in a residential use washing machine (EPA Symbol #: 82544-R).

These silver electrodes are designed to release small amounts of silver during the rinse cycle by an electrolytic mechanism. The registrant further describes that the released silver will treat the clothing such that it retains some residual protection from odor causing microorganisms for a period of time.

The registrant states that the released silver is in the form of silver ions ( $\text{Ag}^+$ ),

The waiver request document for 82544-R (MRID # 477078-04) is subtitled as "ACUTE TOXICITY – NOT APPLICABLE". Furthermore the registrant cited:

- Generic data from the silver RED regarding Acute Toxicity. Acute Dermal Toxicity cited as category III (caution), Inhalation and Dermal Sensitization not applicable.
- The Silver Assembly (generator) only releases silver on the application of electricity within the closed washing machine.
- The Silver ion, as  $\text{Ag}^+1$  is responsible for the toxicity of the metal. This product generates silver ions ( $\text{Ag}^+$ ).
- Sterling silver used in jewelry, cutlery and etc is not considered to be toxic via dermal or oral routes.
- The user has no exposure with the silver in assembly or assembly within washing machine. Infrequent service/replacement of generator (every 10 yrs) would be only by an authorized service technician.

II) FINDINGS: PSB findings are:

It is a reasonable argument that there is very little acute toxicity involved with the silver metal active contained in the Samsung Silver Generator Assembly (82544-E) or the Assembly installed inside the washing machine (82544-R). Furthermore the encasement of the silver electrode plates in the assembly and even more so within the washer poses no significant acute exposure.

The citation of the generic data from the Silver RED only properly addresses the generic toxicological properties of silver metal. Product specific data is interpreted on a "case by case" basis.

PSB finds that the acute toxicity data requirements can be safely waived. There is no perceived immediate or acute toxic effect to individuals in contact with these products.

However this review does not address all aspects of OPP's mission to "Protect Public Health and the Environment..." Study data may be required to address any health effects as the result of chronic exposure to the active ingredient retained in clothes. The environmental fate and effect of the silver released into the waste stream might also be a future concern.

III) The acute toxicity profile for EPA Reg #: 82544-R and 82544-E is currently:

Study	MRID Number Waiver Requests	Toxicity Category	Status
Acute Oral Toxicity	1,2	IV	Waived
Acute Dermal Toxicity	1,2	IV	Waived
Acute Inhalation Toxicity	1,2	IV	Waived
Primary Eye Irritation	1,2	IV	Waived
Primary Skin Irritation	1,2	IV	Waived
Dermal Sensitization	1,2	Non-sensitizer	Waived

1 EPA Reg. # 82544-R Assembly w/washer Waiver Request Document MRID #477078-04

2. EPA Reg. # 82544-E Assembly alone Waiver Request Document MRID #477076-04

IV) **LABELING:** It is appropriate to label the Silver Electrode Assembly with the following "KOROC" statement; because it is a residential use product, the handling of the assembly should only to be performed by trained technicians.

#### **Keep Out of Reach of Children**

The washer with the Silver Electrode Assembly installed must be labeled appropriately for an electrical appliance of this type.

No signal word, precautionary and first aid labeling is required based on the waiver of the acute toxicity data requirements. The use of the signal word "CAUTION" is optional and at the discretion of the regulatory reviewer and registrant. Additional human health and environmental hazard statements are dependent on other risk assessments.

Form Approved OMB No. 2070-0060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Samsung Electronics Co., LTD. 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742	EPA Registration Number/File Symbol 82544
Active Ingredient(s) and/or representative test compound(s) Silver, CASRN 7440-22-4 (PC Code 72501)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, non-food	Product Name Silver Assembly with Washing Machine

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**☐

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

3/5/09

Typed or Printed Name and Title

Samsung Electronics Co., LTD.  
Augustine Kim, Vice President Washing Machine P&D

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



## DATA MATRIX

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## DATA MATRIX

Date: March 5, 2009	EPA Reg. No./File Symbol: 82544-	Page 2 of 4
Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742		Product: <i>Silver Assembly with Washing Machine (end-use product)</i>
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity		Not Applicable		Volume 5
870.1200	Acute Dermal Toxicity		Not Applicable		Volume 5
870.1300	Acute Inhalation Toxicity		Not Applicable		Volume 5
870.2400	Primary Eye Irritation		Not Applicable		Volume 5
870.2500	Primary Dermal Irritation		Not Applicable		Volume 5
870.2600	Dermal Sensitization		Not Applicable		Volume 5
ECOLOGICAL EFFECTS					
Non-Guideline	Wastewater Discharge Report			OWN	Volume 10
HUMAN EXPOSURE DATA					
Non-Guideline	Silver Concentration on Fabric			OWN	Volume 11
APPLICATOR					
875.1700	Product Use Information			OWN	Volume 12
875.1200	Dermal Indoor Exposure			OWN	Volume 12
POST-APPLICATION					
875.2700	Product Use Information			OWN	Volume 12
875.3000	Non-Dietary Ingestion Exposure			OWN	Volume 12
875.2400	Dermal Exposure			OWN	Volume 12
EFFICACY					
Subdivision G, 91-2 (d)	Wash Machine			OWN	Volume 13
Subdivision G, Section 91-4	Fabrics			OWN	Volume 14

Signature:	Name and Title: Douglas Czerwonak, Director - American Research Center, Digital Appliance Business	Date: 3/5/09
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Silver Assembly with Washing Machine - Volume 1 - Page 21 of 29  
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DATA MATRIX

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OWN	Volume 2
				OWN	Volume 2
				OWN	Volume 2
			Not Applicable		Volume 2
			Not Applicable		Volume 2
				OWN	Volume 3
				OWN	Volume 2
				OWN	Volume 2
				OWN	Volume 2
			Refer to EPA Form 8570-36		Volume 1
			Refer to EPA Form 8570-36		Volume 1
			Refer to EPA Form 8570-36		Volume 1
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Waived in the Silver RED		Volume 1
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Waiver Requested	OWN	Volume 4
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Not Required. Refer to EPA Form 8570-36		Volume 1
			Not Required. Refer to EPA Form 8570-36	OWN	Volume 1
			Refer to EPA Form 8570-36		Volume 1

Signature 	Name and Title: Douglas Czerwonak, Director - American Research Center, Digital Appliance Business	Date 3/5/09
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Silver Assembly with Washing Machine - Volume 1 - Page 22 of 27  
Form Approved OMB No. 2070-0060

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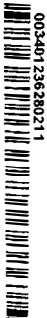
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Date: <span style="border: 1px solid black; padding: 2px;">March 5, 2009</span>	EPA Reg. No./File Symbol: <span style="border: 1px solid black; padding: 2px;">82544-</span>	Page 4 of 4
Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742		Product: <i>Silver Assembly with Washing Machine (end-use product)</i>
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Not Applicable		Volume 5
			Not Applicable		Volume 5
			Not Applicable		Volume 5
			Not Applicable		Volume 5
			Not Applicable		Volume 5
			Not Applicable		Volume 5
				OWN	Volume 10
				OWN	Volume 11
				OWN	Volume 12
				OWN	Volume 12
				OWN	Volume 12
				OWN	Volume 12
				OWN	Volume 13
				OWN	Volume 14

Signature:	Name and Title: Douglas Czerwonak, Director – American Research Center, Digital Appliance Business	Date: <span style="font-size: 1.2em;">3/5/09</span>
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Silver Assembly with Washing Machine - Volume 6 Page 24 of 67 / 0-0060  
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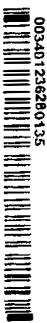
Date: March 5, 2009	EPA Reg. No./File Symbol: 82544	Page 1 of 12
Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742	Product: Silver Assembly with Washing Machine (generic silver)	
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product ID and Composition		Waived in the Silver RED		
830.1600	Description of Starting Materials		Waived in the Silver RED		
830.1620	Description of Production Process		Waived in the Silver RED		
830.1650	Formulation Process		Waived in the Silver RED		
830.1670	Discussion of Formation of Impurities		Waived in the Silver RED		
830.1700	Preliminary Analysis		Waived in the Silver RED		
830.1750	Certified limits		Waived in the Silver RED		
830.1800	Enforcement analytical method		Waived in the Silver RED		
PHYSICO-CHEMICAL PROPERTIES					
830.6302	Color		Waived in the Silver RED		
830.6303	Physical state		Waived in the Silver RED		
830.6304	Odor		Waived in the Silver RED		
830.6317	Storage Stability		Waived in the Silver RED		
830.7000	pH		Waived in the Silver RED		
830.7200	Melting Point		Waived in the Silver RED		
830.7220	Boiling Point		Waived in the Silver RED		
830.7300	Density		Waived in the Silver RED		
830.7370	Dissociation Constant		Waived in the Silver RED		
830.7840	Water Solubility		Waived in the Silver RED		
830.7860					
TOXICOLOGY					
Acute Testing					
870.1100	Acute Oral Toxicity		Waived in the Silver RED		Volume 6
870.1200	Acute Dermal Toxicity		Waived in the Silver RED		Volume 6

Signature 	Name and Title: Douglas Czerwonek, Director - American Research Center, Digital Appliance Business	Date 3/5/09
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Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742		Product: <i>Silver Assembly with Washing Machine(generic silver)</i>
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1300	Acute Inhalation Toxicity		Waived in the Silver RED		Volume 6
870.2400	Primary Eye Irritation		Waived in the Silver RED		Volume 6
870.2500	Primary Dermal Irritation		Waived in the Silver RED		Volume 6
870.2600	Dermal Sensitization		Waived in the Silver RED		Volume 6
Subchronic Testing					
870.3100	90-day oral toxicity - rodents		Waiver Requested		Volume 6
870.3100	90-day oral toxicity - nonrodents		Waiver Requested		Volume 6
870.3200	21/28-day dermal toxicity		Waiver Requested		Volume 6
870.3250	90-day dermal toxicity		Waiver Requested		Volume 6
870.3465	90-day inhalation toxicity		Waiver Requested		Volume 6
870.6200	90-day neurotoxicity		Waiver Requested		Volume 6
Chronic Testing					
870.4100	Chronic Testing		Waiver Requested		Volume 6
870.4200	Carcinogenicity		Waiver Requested		Volume 6
Developmental Toxicity and Reproduction					
870.3700	Prenatal developmental toxicity study		Waiver Requested		Volume 6
870.3800	Reproduction and fertility effects		Waiver Requested		Volume 6
Mutagenicity					
870.5100	Reverse mutation test		Waiver Requested		Volume 6
870.5300	<i>In vitro</i> mammalian cell gene mutation test		Waiver Requested		Volume 6
870.5375	<i>In vitro</i> mammalian chromosome aberration test		Waiver Requested		Volume 6
870.5380	Mammalian spermatogonial chromosomal aberration test		Waiver Requested		Volume 6

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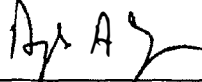
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Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742		Product: <i>Silver Assembly with Washing Machine(generic silver)</i>
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5385	Mammalian bone marrow chromosomal aberration test		Waiver Requested		Volume 6
870.5395	Mammalian erythrocyte micronucleus test		Waiver Requested		Volume 6
Special Testing					
870.7485	Metabolism and pharmacokinetics		Waiver Requested		Volume 6
870.7200	Companion animal safety		Waiver Requested		Volume 6
870.7600	Dermal penetration		Waiver Requested		Volume 6
870.7800	Immunotoxicity		Waiver Requested		Volume 6
NONTARGET ORGANISM					
Tier One Testing					
850.2100	Acute Avian Oral Toxicity	46453301		PAY	
850.1010	Freshwater Invertebrate Toxicity	42650501		OLD	
850.1075	Fish Toxicity – Rainbow Trout	42650501		OLD	
850.1075	Freshwater Fish Toxicity – Bluegill		Waived in the Silver RED		
Higher Tier Testing					
Avian Testing					
850.2200	Avian Dietary Toxicity – Quail/Duck		Waiver Requested		Volume 7
850.2200	Acute Avian Dietary – Duck		Waived in the Silver RED		
850.2300	Avian reproduction		Not Required		Volume 7
Aquatic Organism Testing					

Signature: 	Name and Title: Douglas Czerwolak, Director – American Research Center, Digital Appliance Business	Date: 3/5/09
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Date: March 5, 2009	EPA Reg. No./File Symbol: 82544	Page 4 of 12
Applicant's/Registrant's Name and Address: Samsung Electronics Co., LTD., 416 Maetan-3dong, Yeongtong-gu, Suwon-City, Gyeonggi-do, KOREA 443-742		Product: <i>Silver Assembly with Washing Machine(generic silver)</i>
Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1025 850.1035 850.1045 850.1055 850.1075	Acute estuarine and marine organisms toxicity		Not Required		Volume 7
850.1400	Fish early-life stage		Not Required		Volume 7
850.1300 850.1350	Aquatic invertebrate life cycle		Not Required		Volume 7
850.1500	Fish life-cycle		Not Required		Volume 7
850.1710 850.1730 850.1850	Aquatic organisms, bioavailability/biomagnification/toxicity tests		Not Required		Volume 7
850.1950	Simulated or actual field testing for aquatic organisms		Not Required		Volume 7
Sediment Testing					
850.1735	Whole sediment; acute freshwater invertebrates		Not Required		Volume 7
850.1740	Whole sediment; acute marine invertebrates		Not Required		Volume 7
None	Whole sediment; chronic invertebrates fresh-water and marine		Not Required		Volume 7
Insect Pollinator Testing					
850.3020	Honeybee acute contact		Not Required		Volume 7
850.3030	Toxicity of residues to honeybees		Not Required		Volume 7
NONTARGET PLANT					
850.4225	Seedling emergence, Tier II dose response		Not Required		Volume 8

Signature:	Name and Title: Douglas Czerwonek, Director - American Research Center, Digital Appliance Business	Date: 3/5/09
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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4250	Vegetative vigor, Tier II – dose response		Not Required		Volume 8
850.4400	Aquatic plant growth Tier II – dose response		Not Required		Volume 8
850.5400	Aquatic plant growth (algal) Tier II – dose response		Waiver Requested	PUBLIC	Volume 8
850.4300	Terrestrial field		Not Required		Volume 8
850.4450	Aquatic Field		Not Required		Volume 8
ENVIRONMENTAL FATE					
Degradation Studies Lab					
835.2120	Hydrolysis		Waived in the Silver RED		
835.2240	Photodegradation in water		Waiver Requested		Volume 9
Biodegradation Studies – Lab					
835.1110	Activated Sludge Sorption Isotherm		Waiver Requested	PUBLIC	Volume 9
835.3110	Ready Biodegradability		Waiver Requested	PUBLIC	Volume 9
850.6800	Modified Activated Sludge, Respiration Inhibition Test		Waiver Requested	PUBLIC	Volume 9
835.3200	Porous Pot Study		Not Required		Volume 9
Mobility Studies					
835.1230	Leaching and adsorption/desorption		Not Required		Volume 9
835.1240					
Metabolism Studies - Lab					
835.4100	Aerobic soil metabolism		Not Required		Volume 9
835.4200	Anaerobic soil metabolism		Not Required		Volume 9
835.4300	Aerobic aquatic metabolism		Not Required		Volume 9
835.4400	Anaerobic aquatic metabolism		Not Required		Volume 9

Signature	Name and Title: Douglas Czerwonak, Director – American Research Center, Digital Appliance Business	Date <i>3/5/09</i>
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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dissipation Studies – Field					
835.6200	Aquatic (sediment)		Not Required		Volume 9
Ground and Surface Water Monitoring					
None	Monitoring of representative US waters		Not Required		Volume 9

Signature:	Name and Title: Douglas Czerwolak, Director – American Research Center, Digital Appliance Business	Date: <b>3/5/09</b>
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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Waived in the Silver RED		Volume 6
			Waived in the Silver RED		Volume 6
			Waived in the Silver RED		Volume 6
			Waived in the Silver RED		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6

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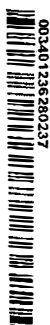
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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
			Waiver Requested		Volume 6
				PAY	
				OLD	
				OLD	
			Waived in the Silver RED		
			Waiver Requested		Volume 7
			Waived in the Silver RED		
			Not Required		Volume 7

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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Not Required		Volume 7
			Not Required		Volume 7
			Not Required		Volume 7
			Not Required		Volume 7
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			Not Required		Volume 7
			Not Required		Volume 7
			Not Required		Volume 7
			Not Required		Volume 7
			Not Required		Volume 8

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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Not Required		Volume 8
			Not Required		Volume 8
			Waiver Requested	PUBLIC	Volume 8
			Not Required		Volume 8
			Not Required		Volume 8
			Waived in the Silver RED		
			Waiver Requested		Volume 9
			Waiver Requested	PUBLIC	Volume 9
			Waiver Requested	PUBLIC	Volume 9
			Waiver Requested	PUBLIC	Volume 9
			Not Required		Volume 9
			Not Required		Volume 9
			Not Required		Volume 9
			Not Required		Volume 9
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			Not Required		Volume 9

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Ingredient: Silver, CASRN 7440-22-4 (PC Code 72501)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Not Required		Volume 9
			Not Required		Volume 9

Signature	Name and Title: Douglas Czerwonek, Director – American Research Center, Digital Appliance Business	Date 3/5/09
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Writer's Direct Access  
**Michael T. Novak**  
(202) 434-4485  
Novak@khlaw.com

April 9, 2008

**Via First Class Mail**

Dennis Edwards  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Mail Code: 7510P  
Washington, DC 20460

Re: Samsung Electronics America, Inc.  
Meeting Minutes: Preapplication Meeting on SilverCare Washer

Dear Mr. Edwards:

On behalf of Samsung Electronics America, Inc., enclosed are the minutes of the meeting of October 17, 2007. Please note that Attachment Two includes a draft letter for your use, per our agreement at the meeting.

If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Michael T. Novak', is written over a horizontal line. The signature is fluid and cursive.

Michael T. Novak

Enclosures

cc: Doug Czerwonka, SEA





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**


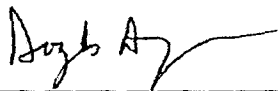
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**SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)**

<b>1. PRODUCT NAME:</b> Silver Assembly with Washing Machine (applies to silver plates only)		<b>2. Reg. No.</b> 82544-
<b>3. COMPANY NAME:</b> Samsung Electronics Co., LTD.		<b>4. SUBMISSION DATE:</b>
<b>5. FIRST SUBMISSION</b> <input checked="" type="checkbox"/>	<b>7. PESTICIDE TYPE:</b> Antimicrobial	<b>10. REGISTRATION</b> <input checked="" type="checkbox"/>
<b>6. RESUBMISSION</b> <input type="checkbox"/>		
<b>8. FORMULATED MANUFACTURING-USE PRODUCT</b> <input type="checkbox"/> <b>or 9. END-USE PRODUCT</b> <input checked="" type="checkbox"/>		<b>11. REREGISTRATION</b> <input type="checkbox"/>
<b>13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN):</b> Marshall Swindell/Team 33		<b>12. REREG CASE #</b>
<b>14. GUIDELINE REFERENCE NO.(GRN)/TITLE</b>	<b>15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES</b>	<b>16. MRID or REPORT NO.</b>

**Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)**

-6302	Color	Metallic	Silver RED
-6303	Physical State	Solid	Silver RED
-6304	Odor	None	Silver RED
-6314	Oxidation/Reduction: Chemical Incompatibility	Not Required. Product does not contain an oxidizing or reducing agent.	
-6315	Flammability/Flame Extension	Not Required. Product does not contain combustible liquids.	
-6316	Explosibility	Not Required. Product is not potentially explosive.	
-6317	Storage Stability	Not Required. Waived in the Silver RED.	
-6319	Miscibility	Not Required. Product is not to be diluted with petroleum solvents.	
-6320	Corrosion Characteristics	Waiver Requested. Refer to Volume 4.	
-6321	Dielectric Breakdown Voltage	Not Required. Product will not be used around electrical equipment.	
-7000	pH	Not Required. Product is a solid.	
-7100	Viscosity	Not Required. Product is a solid.	
-7300	Density/Relative Density/ Bulk Density	10.49 g/mL at 15C	Silver RED

 <b>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY</b> <b>401 M Street, S.W.</b> <b>WASHINGTON, D.C. 20460</b>	
<b>Paperwork Reduction Act Notice:</b> The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.	
<b>SELF-CERTIFICATION STATEMENT FOR THE PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)</b>	
<b>Product Name:</b> Silver Assembly with Washing Machine (applies to Silver Bars)	
<b>Reg. No./File Symbol No.</b> 82544- <b>(if known) or Company No.</b>	
<b>SELF-CERTIFICATION STATEMENT:</b>  <p>I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): <u>Samsung Electronics Co., LTD.</u></p> <p>_____ and that the values of the properties reported are reliable.</p> <p>I further certify that such data was generated in substantial conformity with OPPTS Test Guidelines Series 830 Product Properties, applicable to my product, and in effect at the time of submission.</p> <p>As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."</p> <p>As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.</p>	
<b>Type Applicant's Name:</b> Douglas Czerwonka	
<b>Title:</b> Director - American Research Center, Digital Appliance Business	<b>Telephone No.</b> 847-407-2857
<b>Applicant's Signature:</b> 	<b>Date:</b> 3/5/01

EPA Form 8570-37 (07/JAN/1998)

Atch-2



